HIT Standards Committee
DRAFT Transcript
January 20, 2010

Presentation

David Blumenthal – Department of HHS – National Coordinator for Health IT
—say any more, since we got a late start, but I look forward to hearing your comments on the regulations proposed—the Interim Regulation and also the Notice of Proposed Rulemaking, of course, which also came out on December 30, issued by the Centers for Medicare & Medicaid Services. And this is an auspicious start on a historic journey. And though many other events in the political world are uncertain and hard to predict, one thing I think is pretty clear: that the HITPC authority stands as an established piece of legislation with established resources. We have a good start, and I think, with your help, we'll make the best of it. Thank you.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks, David. Good morning, everybody. I guess we don't have our phone yet. Just for the record, lest anyone think there's anything metaphorical, let the record show that the phone that is not working is indeed not a digital device but an analog device [laugh], so this is once again an analog failure [laugh]. Just feel the need to point that out.

Let me add my welcome, and thanks to each and every one of you for all of your help. It really is pretty remarkable to experience the transition in the new year, the new decade, and on December 30 see published really the culmination of a process that the Administration, David, have led and we've had the privilege of putting a great deal of input into. It really is pretty remarkable, because more and more, I think there are the elements of a roadmap. And is it a GPS? A chart plotter with old landmarks? Not entirely, and you know, that, in a sense, is a metaphor for our future work and really, with publication, not only the opportunity to comment but the opportunity to move forward from a route that sets a trajectory to really something that's more fleshed out and provides guidance where the rubber hits the road, for those individuals who are trying to implement and benefit and deliver improved health care.

I think there is no better articulation of the rationale than Dr. Blumenthal's recent editorial from the December 31 New England Journal. And indeed, just—I hope that everyone on the Committee has read it, but for those who might not have and the public and the audience, I think the first two sentences are really wonderfully metaphorical: "Information is the lifeblood of modern medicine. Health information technology is destined to be its circulatory system." And you know, in fact, I think what—everyone's personal perspective on the state of affairs is that there are elements of systems that are missing and that information technology helps to build that systemness, indeed, to let that lifeblood flow. And so, that article—December 31—it's in the materials; they'll be public from this meeting. I think it should be posted on the Web site. Certainly the December 31 New England Journal is the citation. And the other thing that article does is that even for those of us who've lived day to day with this is that it helps to take one through the differences between what's in the Interim Final Regulation, the work that really conveys the standards; and the Notice of Proposed Rulemaking, which is the CMS document that brings forward the definitions of meaningful use.

There are, in the work we'll go through today, really, a continuity of activity that needs that fleshing out from, you know, completing description of—specifications for content, for vocabulary, for transport of information; of course privacy and security; and then a crosswalk from meaningful use to capabilities and the standards that support them, which implies also a rubric for certification. So more and more—and the reason I draw out an introduction to what we're going to begin to do today is that there is an internal coherence to the material that's available for individuals in the field from all perspectives to use as an increasingly informed roadmap for future direction. Now, as David indicated, we really do have a good bit of work ahead. And for those who read the 556 pages of the IFR, your New Year's present, cover to cover, you will note that there are some differences between the recommendations as we put them

forward and as they came out and some of that. Just having had a history in the Federal Government is simply a reflection of the difficulty of the rulemaking process. And some of it reflects things that you wouldn't want to lock down, because the world changes and there are certain things that you want to cast in concrete and other things that you want to retain flexibility.

But within that, there's further specification of standards in particular areas, and when we reflect—as we're doing with Doug Fridsma, John Glaser, and John Halamka in preparation for this meeting—that we feel proud and glad to have offered "best of breed" in many of the standard domains. At the same time, when one seeks to refine or develop further standards work for the 2013/2015 marks, wouldn't it be nice—wouldn't it be useful to all involved to have a more holistic approach that provides a really harmonized framework into which those standards have developed so that there's a forward continuity that's rational and consistent and, you know, backward compatible as necessary and forward compatible as is required.

The other is that, having offered out this set of specifications for meaningful use and for standards and the implication of the certification process, and with the very real deadlines that are ahead to meet those objectives, what are the most important tools that are necessary for implementation and work there? I teed this up because at the latter part of our agenda [indiscernible]—in fact, Item #9 is future agendas for the Health IT Standards Committee, and we'll have some discussion about that as well as some very specific issues.

Now, the other thing David mentioned was that, indeed, we'll have some particular guidance that John Halamka is going to give us about our response to the IFR, the Interim Final Regulation. But before we do that, let me take care of one item of business; then we'll use that as a segue into the first agenda item, and that is, of course, the approval of our minutes. So let me ask if there are any corrections, amendments or other modifications that anyone would like to offer. [Pause] Having heard none, then let's accept those as written, and many thanks to the Office of the National Coordinator as always for capturing a very extensive and very nuanced discussion.

With that, my welcome and thanks for your work, and let me turn to John Halamka for our charge on response in particular. Go ahead, John.

John Halamka – Harvard Medical School – Chief Information Officer
Great, well, thank you. And good morning, everybody, and happy New Year. And David, I do want to thank you: After we had our discussion on the 30th and I said you are not allowed to release things, I've now noted that ONC is the Office of No Christmas [laugh]. It's the third year in a row! Not your fault before. And also, I'm from Massachusetts, but I cannot be blamed for what happened there yesterday; I am innocent, honest.

Unidentified Man
What time did you vote?

John Halamka – Harvard Medical School – Chief Information Officer
Often [laugh]!

So today, we're going to have a very important discussion about the Interim Final Rule, the Notice of Proposed Rulemaking, and specifically—one, we want to ensure that comments are delivered to ONC by March 1. And as we said, you can deliver comments individually from your organizations, of course, but wouldn't it be great if our working groups could create some consolidated responses. So you'll see the working groups have calls that have been set up already, and the notion of those calls is to work through specifically the Interim Final Rule. I mean, yes, of course the Notice of Proposed Rulemaking is very important. The Policy Committee, I'm sure, we'll be doing quite a lot of review of that. But if we could focus on the Interim Final Rule and the specific comments as to where you think the standards are appropriate or the standards may lack specificity, which could cause issues and problems; where there is specific work that must be done—the working groups and their phone calls would set up a list of comments which then would be brought to this entire Committee on the 24th, and then we can vet them

here and then forward them off to ONC as a collected HIT Standards Committee response, if that seems like a reasonable process—really very inclusive—make sure that everyone gets to view these things, and then, as a Committee, we could take action.

Recognize that, as we'll hear today—that the Interim Final Rule, being a regulation, is actually a rather challenging thing to put together. Wouldn't you love to provide the implementation guidance and specificity that would make interoperability pretty easy and plug-and-play? Well, the problem, of course, is that Federal regulations are challenging to change. And so Jodi, of course, can comment on this—that if we get down to the level of implementation guidance that existed as of January 13, as it's published in the Federal Register, alas, we will then have ossified implementation guidance, because as that implementation guidance gets changed or evolves, the regulation has to be changed.

So I think one tone of the discussion we'll have today is, oh, we look at the Interim Final Rule, which tried to set a bar for at least enough specificity to prevent, you know, every possibility for data exchange, but it has not provided the degree of specificity to ensure complete plug-and-play interoperability. And that was in part to allow innovation and flexibility. And so, what you imagine—the regulation provides a floor, a baseline, a bar, and an implementation guidance would be selected or suggested by this group. Reference implementations will be created by industry. There will be mechanisms by which that specificity will evolve. But you know, when I had heard that there were, you know, constraints that you had in putting this document together, that certainly provided a nice way for me to interpret the IFR as not purposefully taking out specificity but trying to actually allow evolution and allow the standards development organizations and this group flexibility as it provides implementation guidance and reference implementations going forward.

So I think it'd going to be a great discussion. We'll hear also what the differences between our recommendations and the IFR said specifically. And then after we hear that presentation, I'd like to go around the room and start with our working group chairs and ask for some of their initial thoughts on what issues are. And so, for example, in the—you know, Jamie, not to put words in your mouth, but, "Oh, HL7 2.5.1 is a nice standard, but without implementation guidance, we can't actually ensure that labs across the country could actually exchange data." You know, these—the kinds of issues that we'll go around and we'll try to raise and just get a feeling for the work ahead.

The IFR also does provide us with several homework assignments, and so we will need to catalog those, such as, "We will allow CCR and CCD, but HIT Standards Committee—over time, wouldn't it be great if it was one, whatever that is? Can you figure that out?" [Laugh] And so, if there is homework, we'd better make sure we know what it is and that, as we talk in the latter part of the meeting about our work for the next 6 months—that it's our agenda.

So look forward to a very good meeting today, and turn it back to Jonathan.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Well, thanks, John. And indeed, a terrific guidance, and look forward to that discussion and, indeed, both our formal response and—I'm sure that our—individually, we also have input that we want to offer in this process that, I think it's very important to acknowledge, has been a very open and public process; the FACA, Federal Advisory Committee Act, really holds us to that. And this is a really important dialog, and the process is set up just for that input. So really encourage that input, which really, you know, provides the direction and guidance that's so helpful to come with the best product.

Toward that end, let's get on to the discussion of the Interim Final Rule. And we've got Farzad Mostashari and Doug Fridsma from the Office of the National Coordinator to walk us through. And then I really look forward to the discussion that will follow that. Doug Fridsma's here, and we'll start that discussion.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Thanks, Jon; delighted to be here. I'm going to actually ask Jodi Daniel to join me here. I think Farzad is on his way, or he may be otherwise detained, so we'll be able to continue this discussion otherwise.

So what I've done in trying to prepare for this and to sort of provide some discussion is—you all have some slides in your package; I just want to step through them. I have not gone and provided you with a suite of 30 or 40 different slides. I think what's most important is that we can sort of frame up some of the issues that we addressed in putting together the IFR and point out some of the key features—some of the places in which the regulations that were adopted by the Secretary differed in some sense from the recommendations of this group and then, at that point, provide us with a lot of time that we can have some discussion and answer more specific questions.

So I think the things that—in developing the IFR, there were some principles that really guided both the certification criteria and the standards. Within this group, we heard very clearly that we wanted to make sure that a certified EHR had the capability to support meaningful use, and that we wanted to make sure that what we had within the criteria in the IFR would support the providers in achieving meaningful use. We wanted to make sure that we had at minimum those kinds of functionalities.

What you'll notice as well is that we wanted to make sure that these things could be tested objectively, because we wanted to be able to make sure that the criteria that were in there were things that the certification process, which will be described in an upcoming NPRM, could be evaluated and we could develop criteria that people could build their systems to. We did not include all the possible functionalities that an EHR could provide. We chose those elements, again, that support meaningful use and that we could test objectively. So, for example, usual—you know, the kinds of things that an EHR may need to provide, which may be, you know, the ability to document a note or the like—those things aren't specifically part of the certification criteria, but we want to be able to make sure that people have the tools and the resources to meet the certification criteria. And so it was described at a very—sort of the minimum set that would get us there.

I think, with regard to the standards, this is the first of the regulations that we're required to produce, and so we want to progressively increase our capacity to develop and to standardize. In some situations, we wanted to make sure that we did not come up with new requirements. So, for example, when it came to the security and the authentication criteria, we did not want to create health care-specific requirements, but instead to leverage the work that's been done in other agencies, like NIST and the like, and to realize that there's a lot of different ways that we could do authentication. Many of the things that are described in terms of secure transport are described in a functional way that provides an opportunity for innovation about how that might happen, setting the bar in terms of what people are expected to do.

On the other side, when it came to the things related that were really health care specific, when we talked about some of the terminologies and some of the packages—the transports that were out there, we really were trying to push the industry to adopt specific recommendations and terminologies. And so, we attempted to be, in some cases, more specific around the terminologies, and we hope to get feedback from this group about how we can continue to get additional specificity around the standards around vocabularies, terminologies, and the packages that we send, but still allow a certain amount of innovation when it comes to the security functionalities and the methods for transport so that the industry can innovate around that and we don't sort of lock people into a particular way of doing things.

To give you a sense of the process that we went through in developing the IFR, much of what we had—in fact, all of what we had was guided by the meaningful use objectives. And so, what we needed to do is, we needed to be able to say—to take a look at the NPRM for meaningful use, establish certification criteria that would allow us to test some of those meaningful use objectives, and then to develop the standards that would also be involved in the certification criteria and the exchange of data. So, for example, if one of the meaningful use objectives is the ability to send a prescription from a provider to a pharmacy using an electronic means, our certification criteria said that that EHR technology has to have that capability, and so we have to be able to have the ability to transmit an electronic prescription. And to do that, we have to have a particular standard, and that standard was the NCPDP SCRIPT 8.1 and 10.6. So we wanted to be able to start from meaningful use objectives, establish the certification criteria, and then put together the standards that would support that criteria. Similarly, the meaningful use objective was to provide patient summary record—to be able to kind of generate that and to transmit that for the purposes of consultation or the like. And so the certification criteria said that we have to be able to

electronically submit a patient—or transmit a patient care summary record, and that has to be something the EHR should be able to do. And the standard that the Secretary adopted included both the Continuity of Care Document (CCD) as well as the Continuity of Care Record (CCR), and so, that has to be the way to do that. We also enumerated some of the vocabulary standards within the CCD that needed to be transmitted.

Finally, as another—as the final example here, electronically submitting data to immunization records—again, that capability had to be testable. And we identified both HL7 2.5.1 as well as HL7 2.3.1, as well as the CVX code set, as the standard to support that.

Jodi Daniel – ONC – Director Office of Policy & Research
And can I just make one point? For every meaningful use objective, we do have a certification criteria to make sure that the technology is capable of supporting meaningful use; but for every certification criteria, there isn't a standard. We only have the standards where we thought they were appropriate. So I just wanted to make that point, because this crosswalk looks like it's a one-to-one.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Yeah. Thank you.

So we took our organization of the IFR from HIT Policy and Standards Committees, in the sense that we described content exchange standards, such as clinical summaries, the prescriptions; vocabulary standards that describe problems, procedures, medications; transport standards between systems that include things like REST and SOAP; and then privacy and security standards that span all the other standards as well and are described in the IFR for authentication access control encryption using sort of a functional description of those as well.

So these slides are difficult to read on the screen, but hopefully people can read them in the handout. I've got my—don't have my glasses on, but I can—we can take care of this. What I'd like to do is, I'd like to just point out some of the differences that we have, as well as what we really incorporated from this group to try to take a look at things. If you go through the list of the content exchange packages, we really took to heart the recommendations that came from this group and tried to include those in our Interim Final Rule.

I think one of the places that we probably want to have some discussion and input from you and the community is around the patient summary data package. In that particular one, the recommendation was to include CCD and CDA template or HL7 2.5.1. What was adopted by the Secretary was CCD or CCR as part of the certification criteria. But we spent—we put in the regulations fairly strong recommendations that we want to begin to constrain the choices as we go forward and that we will rely on continued discussion with the HIT Standards Committee about how best to do that.

With regard to the quality reporting metrics, the recommendation there was to use the CMS CDA, and what was adopted by the Secretary was the CMS PQRI. But we believe, again, that as we move forward—that we will likely move into different standards and that we will get feedback from this group in terms of how to do that fast and to get feedback.

With regard to some of the vocabulary and terminology specifications, there were a couple of situations—and I'll just use as an example the medication allergy standard. The recommendation there was local or proprietary codes or candidate Stage 2 standards. The challenge that we have there is that if we were to provide, as a certification criteria, the option of a Stage 2 standard, that has the regulatory effect of adopting that standard at that time. And we felt that that was—that may present challenges with regard to the regulation. And so, what we did is, in those circumstances, we did not specifically adopt a standard but did message that we will need to do that, and with dialog with this group and with input. We considered things like for units of measure to move to UCUM, medication allergies to use—to move to UNI—and so, that will be part of the program as we move from 2011 to '13 to '15, when we will begin to adopt more specific standards there.

One of the things that we did that was, again, a deviation was with regard to medication lists. There the recommendation was local or proprietary codes or candidate Stage 2 standards. And one of the things that we recommended and was adopted by the Secretary was that we would adopt any code set that is in the—that is mappable or is in the RxNorm data source providers and that are identified in the—identified by the NLM as being a complete data set integrated with RxNorm. And I think that was an effort to begin to push so that we believe that one of the Stage 2 standards that is under consideration is RxNorm, and that if we begin adopting code sets that are able to get us to that transition, that becomes a useful kind of staged approach to help us in that regard.

We also, with regard to laboratory orders and results, tried to provide some additional guidance as well. There the recommendation was local or proprietary codes or candidate Stage 2 standards. And knowing that the Stage 2 standard was LOINC, and that was the one that was under consideration, we wanted to raise the bar a bit for the certification criteria that says that a certified EHR needs to be able to accept LOINC codes if they're provided to them. It's important to note that for meaningful use, if there isn't the ability to accept—if you don't have a laboratory system in your local region that can send you a LOINC code, you—that's sort of a separate issue with regard to the provider. You can still qualify for meaningful use, but your certified EHR needs to have the capability of receiving that when they're available. And so, because our regulation is really focused on EHR and not on laboratory systems, this was a mechanism that we could really begin to make sure that the LOINC codes, when available, can be used by those certified EHRs.

I think the only other place that we have a little bit of variation, at least on this slide, has to do with the public health surveillance and reporting. Actually, I take that back; that is—in fact, we adopted this directly. Next. [Pause] Can we go to the next slide? My clicker isn't working. [Pause] Can we go to the next slide? Thank you. My clicker isn't working now. [Pause] There we go. Okay.

With regard to transport, security, and privacy, we adopted the recommendations of the Committee to use the transport REST or SOAP, a sort of an architectural framework to work with. When it came to some of the other standards, one of the—what we did in the descriptions in the IFR—the recommendation, for example, for encryption and decryption was the FIPS 197 Advanced Encryption Standard (AES). What we really did there is, we tried to take that standard and describe it as a functional specification and provide a floor to the technology, in a sense to provide an opportunity for people to meet the criteria that's described here, but then to be able to, if need be, provide greater encryption or greater security around this rather than creating both a floor and a ceiling by adopting a very, very specific standard.

And so, throughout the transport, security, and privacy recommendations, we took the recommendations and then—took those and described them in a functional way, with examples of the kinds of things that would support or that would meet that criteria. So for encryption and decryption for exchange, we talked about using—the recommendation was the transport layer security, using TLS. We described that functionally and gave TLS as an example, and went through all of the recommendations in that way to kind of give people the opportunity to create a floor, but to provide innovation and higher levels of security if need be.

The same is true here with the authentication that was in there. We took both the HIE recommendations about the XUA and EUA profiles and there tried to describe those in a functional way so that people would have the ability to do stronger or tighter authentication as well, you know, as part of this.
And this is the last slide, and I think then we can open it up for specific questions and discussion. I think the thing to recognize here is that what we're trying to do is sort of build together the standards and the functionality that we would like to see for a certified EHR technology. Those things together become part of the certification criteria and, combined with the NPRM that's coming out on the certification program, will lead to the ability for us to identify certified electronic technology that will help support meaningful use and data exchange. And so, this particular IFR is sort of the first of those building blocks and the first step towards getting us towards that interoperability and the—and developing a program for the certified EHR technology.

And I think—I'm sure the Committee has a tremendous number of questions, and I think there will be—I hope—good discussion that we have. And so I welcome, at this point, questions.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Why don't we start with some questions for Doug, and then we'll move on to a discussion of first reactions that you have to the Interim Final Rule and some of the changes between our recommendations and their regulation. Questions? [Pause] Put up your cards in the usual fashion. Wes! Good to see you! [Laugh]

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Kind of late with my card today, huh? I have a few questions, one at a time; is that good? You talked about—John, I think, talked about evolution outside the regulation. And I certainly think you've done a wise thing in trying to separate the glacial pace of regulations from the pace it takes to deal with the adoption issues that arise when you're rolling out standards. What is the process for evolution outside of the regulation that you anticipate?

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Well, I think I can probably do that, in some sense, by example. We've adopted CCD and CCR as package frameworks for exchange. From this group, there was a lot of discussion about pros and cons, and there's been input not only from this Committee but from lots of other public comments that have come in through this process, touting the benefits of one versus the other. I think that as we move forward, we will see what—which of those standards are capable of providing more functionality as we move forward from 2013 and 2015. We'll see perhaps tools that will come on board that will make one process easier than the other. We may say—see differences in adoption rates with regard to that. So I certainly think that one of the drivers that we have to be very cognizant of is kind of what the market tells us in terms of what is—what are the things that people find useful for the exchange of information. So I think that's one.

I think one of the things that we certainly don't address here are what a particular organization may decide to do from a policy perspective. It may be that an organization will say, "We have a certified EHR; it can do two different ways of exchanging this information, but we will choose within our organization to do one, because we find value in that as well." So there are policies that different organizations may impose apart from this that says, "If you want to talk to us, this is the way that we would prefer that you do that," within the auspices of the IFR. So I think it remains to be seen how that all plays out, and this is—of course, we've got a public comment period about the IFR as well, and I think that will provide us input in terms of what things we can improve and how we can get to adoption of technologies for certified EHR and support meaningful use and exchange of information.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
What I didn't quite get from that is, do you envision a mechanism, other than issuing the next regulation, for narrowing the choices, thereby increasing the probability of interoperability? Or—I mean, it's just been a problem since HIPAA; this is nothing new; I just—have you figured something out yet? [Laugh]

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
I think, you know—I guess the answer's, "Have we figured it out? I don't think anyone has figured that out yet." But I do think that for us to be successful, it's going to take using all of the different levers and motivators that we have. There will be market forces; there will be regulatory forces; there will be certification criteria; there will be policy, and I'm speaking of that not just from sort of a Federal policy, but I'm thinking about local policy, about what people will want to do about all of that. Ultimately, I think that we have to use all of the mechanisms that we have to kind of get to where we want to go. And it isn't all going to happen in regulation, and it isn't all going to happen in certification. There are going to have to be external mechanisms that will drive this as well. So the answer is, "Do I have—do we have the solution? Not yet." But we're—I think we need to see what happens as people begin to move forward as we continue to constrain the choices.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

So given that there are, in the meaningful use NPRM, specific levels of lab results that must be imported in structured data and the transfers of patient information that must be reached, does the inability of potential recipients of incentive money, because of local problems adopting a standard, then constitute a market force? Is that…?

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
I'm sorry?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Does that constitute a market force? Is that—I think—let me state an opinion: I think that, given the volume of labs that are not—that don't come from the major lab vendors, there not being a specification for exactly how to send lab results will create difficulty for some organizations in meeting that meaningful use requirement. That might generate the kind of market consensus that you're describing, as—particularly if they lose Year 1 incentives. Is that—I'm just struggling with where is a forum to get that decided; that's it.

David Blumenthal – Department of HHS – National Coordinator for Health IT
If I could jump in here…

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Yeah.

David Blumenthal – Department of HHS – National Coordinator for Health IT
So this is clearly not an area of my personal expertise, but as I sit at the knees of many of you and listen, what I have come to envision is a kind of dialog between market and regulation. As market forces identify solutions, they can be adopted by regulation if needed to systematize them. And where the market creates a demand for government to intervene, then government can also intervene. The sense that we had from you and from others in the community is that, while there are some areas of consensus around standards, there are some areas where we could adopt standards and they wouldn't be standard, because people weren't ready to use them and accept them, and that the cake wasn't cooked, if you will. So we've—the Congress, in its wisdom, has created a set of financial incentives that reward certain behaviors. When those financial incentives become available and the market moves toward doing the things that are necessary to get those monies and can't do it without our help, with your advice, we will stand ready to help them.

John Halamka
I've got a question: When you look at the preamble versus the regulation, there's an "e.g.," for example, that says, you know, "e.g., this standard or that standard," and the regulation doesn't include the "e.g." And one of the things Dixie and I had been wondering: You enumerate the standards for, let's say, Jamie's area, clinical operations, and you don't enumerate the standards on privacy and security. And so, just so we're clear, it is true from a regulatory standpoint that HL7 2.5.1, without specific limitation guidance, is in the reg, not just the preamble, but the statement of TLS IP set—what, IP version 4, IP 6—is not in the regulation; it's just in the preamble as an "e.g."

Jodi Daniel – ONC – Director Office of Policy & Research
Yep, that's correct; that's a correct understanding.

John Halamka
Okay.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
So the implication is, when industry moves from HL7 2.6, you know, and down the road to version 3, that will require regulatory change.

Jodi Daniel – ONC – Director Office of Policy & Research
That's correct.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
So it is perceived to be that moving from 2.5.1 to 2.6 is far easier than moving from, you know, TLS to the next version of TLS, or AES to the next encryption standard that comes down the pipe.

John Halamka
Or the transmission will evolve much more quickly?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yeah, that's the implication. You know, and if you look at how quickly, for example, TLS has come—or AES—and those encryption standards change for symmetric encryption; they change maybe every, oh, 6–10 years [laugh]. I mean, it's a long time between changes in NIST-certifi—NIST-approved symmetric encryption, and I'm wondering why that's perceived as a quicker, you know, more frequent change than HL7 2.5 to 2.6

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
I guess—what we tried to do—and I think authentication is a good example of that—we tried to describe, again, the features that we wanted to take a look at with respect to certification, so that the functions that the EHR needed to provide to be considered certified had to meet the descriptions that we have there for authentication, or that—for the encryption, it had to have the same sort of, you know, X-block symmetrical encrypt—you know, we describe that directly. I think it was a choice that was made: that for those things that were very health care specific, we wanted to be more specific and try to adopt very specific standards around that, and so sort of enumerate its 2.5.1 or its 2.3.1 or whatever it was. But when it came to the things that were sort of more broadly and—in which we couldn't necessarily say in health care, "That is within our domain and the thing that we have to take ownership of." In those situations, we tried to describe things from a functional perspective. And you know, this is something that—we welcome feedback from the Committee and from the public about those choices, but we tried to make sure that by describing things functionally, we'd be able to—you know, if there was a new method for authentication, for example, that we could set a floor and allow innovation in different versions to come down the pipe.

Jodi Daniel – ONC – Director Office of Policy & Research
And Doug can correct me if I'm wrong, but the other thing was where (ahem)—excuse me—where the standard affected interoperability of information—information exchange, we were more concerned about having a specified standard identified, as opposed to, for instance, in the security realm, where that wasn't as much of a concern.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Yeah, the—many of the security and privacy standards are there to provide functionality that providers can use, and we recognize that security and privacy is not so much a standard as it is a process. And so we wanted to make sure that we provided those building blocks, or at least a specification of what those building blocks should look like.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Well, I do have some comments about authentication in general, but going—the specific topic of whether it's an "e.g." or whether it's a specific standard—we do, at least based on the input that I—my own personal opinion and the input that I've gotten from our workgroup so far, we think it's a pretty good idea to specify it functionally to allow—and to get the standards in through implementation guidance, reference implementations, open-source components, et cetera, you know, because it does allow you the—more regulatory flexibility and to allow for innovations—allow for flexibility. We agreed with that. But I would say that, you know, in my experience watching HL7, you're going to encounter the same issue with HL7 that you do with the secur—you know, with the security standards, because they do change certainly as quickly as, if not more quickly than, security standards.

Jonathan Perlin – Hospital Corporation of America – CMO & President
[Indiscernible, apparently calling on the following speaker]

Anne Castro – BlueCross BlueShield South Carolina – Chief Design Architect
I wanted to talk a little bit about the terminology "EHR modules" versus "complete EHRs." That—in South Carolina, that's caused a lot of confusion from some exposure I've had regarding, as a big example, the eligibility requirement in meaningful use and the claims submission in meaningful use. And as I understand it, there's a lot of EHRs that don't include those components; they're independent as part of the physician office systems. So that—now the question is, do I have to put those two components into my EHR to get it certified? Do I have to meet the requirements more broadly on my PMS that I didn't think I had to worry about? There's a lot of confusion around that, so it kind of took me by surprise. I mean, we just hadn't talked a lot about complete versus modular within the workgroups. So specifically about that, if you could share your thoughts on that…

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
So I just want to make sure I understand the comment or the question. Having these different modules—so, for example, if you have an electronic health record system that provides a certain degree of functionality and you have another component, a billing component or whatever, that provides other kind of functionality, part of the reason to be able to have kind of the ability to certify things as modules is that that would accommodate that—that if it wasn't a full suite in one system, we'd have the ability to say you have two components, both of which are certified, and that together they give you the functionality that you need to meet the requirements for meaningful use.

Anne Castro – BlueCross BlueShield South Carolina – Chief Design Architect
But the level of certification on the claims submission and eligibility as a noncoupled component, how much of all of the standards have to be met by that tool which—I don't think anybody was thinking they had anything to do with any of that. But now that it's in meaningful use and it is a component piece of a complete EHR, does that mean I've got to do a whole lot more work on my PMS system tools that are already in place? And in some places, there's no expectation of change. I can't speak for the vendor community, but…

Jodi Daniel – ONC – Director Office of Policy & Research
Okay, so let me take a stab at this. The—for an entity to qualify as a meaningful user and qualify for the incentive program, they both have to have certified EHR technology and then meet the requirements of meaningful use. So to be certified EHR technology, it has to meet all of the standards and functionality that we specify in our regulations. It doesn't mean that each component has to meet all of the standards and criteria; it means as a package it has to meet all of the standards and criteria. So for instance, if you have an EHR that has everything except for the eligibility requirements, and then you have a separate billing system that just is focused on the eligibility requirements, the almost complete EHR would be certified as meeting everything but the eligibility, and that would become a certified module. And then your billing software would also have to be certified as needing the other components—the other criteria so that, as a suite, it has met all of the criteria and standards.

Anne Castro – BlueCross BlueShield South Carolina – Chief Design Architect
Does it have to meet all of the security and privacy standards?

Jodi Daniel – ONC – Director Office of Policy & Research
We—that will be further elaborated in our certification process NPRM [laugh].

John Halamka – Harvard Medical School – Chief Information Officer
Sounds like we've had a lot of internal chatter about that, because the question, of course, for Dixie—sometimes we talk about internal systems; sometimes we talk about external systems. And so, if, in fact—let's just imagine a modular EHR includes a quality warehouse reporting component that sits inside your data center as a locked database with no communication outside to the world. You know, where does, in fact, that have a security element other than beyond "Oh, is the data in a mobile device? Is it going to be moved over a network and therefore need to be encrypted as it goes in?" or something like that? So I think the answer is, it depends. And that's why looking at your next rule will be very informative to us.

Jodi Daniel – ONC – Director Office of Policy & Research
And we'll probably welcome your input on that as well, because that is—it's a challenging issue.

John Halamka – Harvard Medical School – Chief Information Officer
Great.

Anne Castro – BlueCross BlueShield South Carolina – Chief Design Architect
And finally, just some feedback on the whole approach of waiting to see which way the industry goes versus telling them more up front. We had a—we're working on our State HIE in South Carolina, and most vendors in that geography are in that room, and they're very frustrated that you're not just telling them what to do. And I don't think that that message is very clear; they're still waiting. They're still waiting and waiting, and I'm afraid it'll compromise our objective of getting adoption. So just want to point out that there is a—they're sitting there waiting for something specific—anything—"Tell me 2013 now"—anything, and we're waiting until they do something so we can tell them what they did. So that whole thing is just very frustrating from a combined audience of vendors and State HIE people.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Dick, did you want to say—?

Rick Chapman – Kindred Healthcare
I was going to say you should tell them to comment.

Anne Castro – BlueCross BlueShield South Carolina – Chief Design Architect
Well [laugh], I told them to read Dr. Blog's blog, because I thought it was very meaningful information, but I have to l—to comment, exactly.

John Halamka – Harvard Medical School – Chief Information Officer
It isn't that everything you specified is overly general. There are just some specific areas. So I comment on this in my blog, and if you go to do e-prescribing today, you pretty much described everything you need for an e-prescribing transaction. It's maybe the clinical summary that is lacking specificity, and therefore we hope reference implementations and open-source tools and the industry comes together around this and that sort of thing. That's—I think you put it very well. It's what's the balance between regulation and then industry innovation that is going to provide us with a set of what we'll call industry-created standards or implementation practices that make it very easy for your HIE to decide what to do.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Cris.

Cris Ross – MinuteClinic – CIO
So I wanted to make a quick comment about what Anne was discussing and others and then ask a question. The comment about EHR technology and so on is, I think there may be a nomenclature issue that you may be able to resolve easily in some ways, because EHR previously was thought as the entire suite of the technology used by a practice. A practice like mine is what has been discussed here, where an EHR is understood to have only a subset of that functionality. And a broader term is probably needed for all the technology within that suite. I also appreciate the fact that the regulations did not speak to certifying the interoperability between those components within a practice. I think that's a herculean task and should be left to systems integrators rather than regulations, so—comment going forward.
My question is around comments that you're receiving from the public, to the extent that you can talk about it. I think this Committee would benefit from seeing as much as possible of that public comment, and I wonder if you could tell us how we might be receiving that comment as it rolls in.

Jodi Daniel – ONC – Director Office of Policy & Research
The comments are all—will all be publicly available. I don't know that we've received any yet; I haven't looked. But all the comments will be publicly available on Regulations.gov, and we can also—if the Committee wants, we can help make some of those more easily accessible to folks or, you know, provide

some digest once we've digested them, although that will probably be after the comment period closes—that we'll actually be digesting those comments. But they are going to be publicly available on the Web.

Unidentified Man
Hopefully they'll be enough that a digest will be useful to us, so…

John Halamka – Harvard Medical School – Chief Information Officer
But as we meet as a group in our workgroups to actually be able to look at common themes—and then I'm sure that will hel—you know, give us guidance for our future work over the next several months.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Walter.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Yeah, thank you. I have three comments. The first one is picking up on some of the discussion about privacy and security, particularly security. I think it's probably understandable, but it's also probably important to clarify that in reality, the quote-unquote "standards" that have been identified for security are really, when you look at them, statements of the types of standard applications that can be used. So whereas in other areas the specificity is such that it ta—tells you the version of a particular standard, in privacy and security or in sec—security basically is a statement; it's really a—you know, an encryption is a—you know, an encrypted and integrated, protected link must be implemented. So it's a general statement that describes different types of possibilities. So as I think had been pointed out, it is probably very difficult to today choose a particular technology, a particular application, a particular version of something, about encryption or about authentication or things like that.

So I think I understand that perspective, and I think we're seeing support for that direction. The challenge is in the interoperability side, because in reality, looking at encryption, for example, there could be 25 different products that—or 150 different proprietary-type products that could meet that general statement stated in the rule. And at the end of the day, that's not going to necessarily promote interoperability, except that, of course, if I used, you know, a particular product, I expect my trading partners to use the same product. But then the same will be expected from all my trading partners from me, and so I would have to have the capability of handling many different types of technologies that meet the general statements that have been written into the rule.

So the concern that I would express is perhaps on the interoperability directions of the statements and the potential that they would, rather than provide interoperability—would have the risk of not pursuing interoperability. So that's just a comment I leave. I guess I don't know if you have any thoughts or any reactions to that.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Well, I think those are the kinds of comments that we need to hear as we take a look at the regulation. Some of the adopted privacy and security standards do span organizations, and I think, you know, comments about that interoperability are something that we need to hear from this Committee and from the public about. Some of the standards are functions that we want the electronic health record to have as a capability, realizing that some of those may not actually span organizations. And so, kind of getting feedback and figuring out which one of those would be the right ones to change or modify, I think, is feedback that we would welcome.

John Halamka – Harvard Medical School – Chief Information Officer
So Walter, what I hear from the industry is that every time, in a regulation, you put the word "or," it actually means the word "and," because if you say "TLS or IP version 4, IP 6—or IP version 6," it means the vendor has to support all of them.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO

Yeah, and of course, the list is not exhaustive, as this "e.g." is a couple of examples which opens the door for many of it. So—but I think that's going to be very valuable to hear from the industry and certainly, I guess, will provide some comments around that.

The second comment I have is about, well, X12, when we deal with HIPAA, back in the HIPAA days, and we're still in those days, I guess, in some [laugh] respects, we always used to say that the devil is in the version [indiscernible] the devil's in the detail. The devil's in the version, and I have two comments about X12. I think that the first one is something of what has been said with respect to the expectation of meaningful use and the incorporation of these two administrative transactions, eligibility and claims, into the mix. It's—there is some concerns, I guess, out there that I have been hearing in various venues about the meaning of having to, #1, certify my PMS, perhaps, my practice management system, to, you know, be capable of doing X12 transactions so that then I can add that into the package of all the different other modules that I have, you know. Traditionally, of course, if PMS has never been seen really as an electronic health record technology—now, I do like the direction that we're taking into integrating this concept of administrative and, you know, business or billing type of systems and the clinical systems, because in the end, it's all the same data. And so the direction's good, but the reality is, most of those are still very distinct in most settings, whereby, you know, my claims and my eligibility are conducted by something, you know, that I have on a different computer and communicates it, and all my electronic health record activities is outside of that.

So the—you know, and I know we're probably not yet commenting on the meaningful use regulation, but in the IFR, we set the standard that administrative transactions, you know, being this—the ones that have been set in a meaningful use—we say that—or is said that, you know, the expectation will be that 80% at Stage 1 of the claims and eligibility will be conducted using those standards. So the question—and I know the clarification that I would expect would be needed is that—is the intent that the electronic health record technology actually perform those transactions natively within the system, because that's not how most of those transactions happen today. In other words, if my environment has to meet the 80% claim to meet the meaningful use, which of my EHR components have to do that? And again, I think it had been somewhat clarified already, but there is—

John Halamka – Harvard Medical School – Chief Information Officer
That's a good question. So suppose, in the spirit of everything you've written, that I have a practice management system with no capability of supporting the X12 standards. So I use a proprietary interface to a third-party intermediary, and the third-party intermediary uses all the 4010 or 5010 standards. Well, I guess the question would be, given that what we're certifying is the combination of the PMS, the EHR, and the third-party intermediary, that collection meets the level of the standards you've required. Is that okay?

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Well, yeah, that's the question [laugh]. Is that the kind of—because X12 trans—I mean, administrative transactions don't happen the way, perhaps, that EHR-like transactions happen, where the EHR itself is capable of generating a CCR or CCD and sending it out directly and the other one picks it up. There's no intermediary or in-between. In the administrative transactions, there's currently a lot of that type of intermediary exchanges, and so that's—so from your perspective, what would be the intent or…?

Jodi Daniel – ONC – Director Office of Policy & Research
So I'm going to punt to get on this one. This is not something that's addressed in the standards and certification IFR but will be—is something for the certification process regulation. But your feedback on that is actually very helpful and welcome and is something that we will address or need your input on in that—in the process for certification and what can be certified and how it can be certified.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
But I think it would be very critical in the meaningful use rule, because that's—the meaningful use rule is the one that sets the stage for me having to comply with, you know, meaningful use by doing 80% of my

claims, you know, using the standard, but through the EHR-certified technology. So by the—you know, in the meaningful use rule, there needs to be that type of a clarification.

Jodi Daniel – ONC – Director Office of Policy & Research
And the other point—I mean, if you wanted to comment on this, in our rule, we do have a definition for certified EHR technology, and you may want to comment on it in that context of what should be included in the definition of certified EHR technology. And I think, from what I hear you say—is that the intermediaries need to be considered as part of that whole, so…

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Yeah, but that's—that would be what—

Jodi Daniel – ONC – Director Office of Policy & Research
Yeah, and again, welcome your comments on that, either as the Committee or individually.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Yeah. The—may I—?

Jonathan Perlin – Hospital Corporation of America – CMO & President
Well, we are running out of time for this section. I wanted to open it up to our co-chairs and then throw some additional initial first reactions. And so, sorry about this, but why don't we—because we are going to go through a process with our workgroups of getting you detailed comments—just want to get some high-level reactions to the IFR. So why don't I start with Jamie, based on your initial read—your initial reactions?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay, well, thank you. So actually, many of my initial reactions have already been aired here today. There are a couple things, Doug, in particular in your chart that shows the recommendations versus what's in the rule. A couple of very minor points I did want to point out is that, in terms of the content exchange for quality reporting, we did recommend out of this Committee the use of PQRI in Stage 1, as well as the quality reporting data architecture, with a proposed migration to the quality reporting data architecture or CDA-based quality reporting for Stage 2. So I think that would be just a clarification there.

And then one other thing on the vocabulary side that I would note is that we did actually recommend medication allergies—the vocabulary for medication allergies should be at the clinical drug level using RxNorm, and—whereas obviously nothing was adopted there for Stage 1, but for Stage 2, that's done at the ingredient level. I would just—that was—actually was a discussion point for us in the Clinical Operations Workgroup, where we actually had that discussion and made a recommendation specifically to do that at the clinical drug level rather than the ingredient level, because that's essentially the way things are practiced today if somebody's allergic to penicillin—if they're allergic to penicillin, not the four inert ingredients that you want to do sensitivity for.

But—so back to sort of the broader point, then: The one, I think, question that I would have is on the degree of change that would be useful to see in comments from Stage 1 to Stage 2. In other words, where particular standards are adopted in Stage 1 and we had previously recommended a path towards perhaps something different in Stage 2, what would be most useful to hear from this Committee in terms—and what degree of change really is going to be acceptable once there is good implementation of a particular set of standards? How material or how—you know, "How big can the change be to Stage 2?" is really my question.

John Halamka – Harvard Medical School – Chief Information Officer
As an example, on the quality side, the way things are written now is, 2011 is at a station, 2012 is PQR XML, and 2013 might be QRDA. Well, gee, you know, doing three different things in three different years—you really want to do that? Maybe you skip one of those intermediate steps.

Unidentified Man
So the comment is, I guess the feedback that's helpful for us—I mean, one of the reasons that, in some of the circumstances, we did not adopt a standard but instead signaled that we would get input from this Committee for 2013 and 2015 was to address that issue—that we didn't want to have multiple hops that people would have to do, at the same time trying to signal and nudge and move the industry in a way that would be helpful. I think the kind of feedback that's going to be the most helpful with this is, as we think about raising the bar, and as we think about moving towards more explicit standards that may not currently have a widespread adoption, having data and having information about what's out there now, what—you know, the difficulty of this—the more we can base the comments on the IFR in experience and data and things like that to frame it in that way really provides us a lot more value, in terms of the kinds of changes or the kinds of modification that we can consider. It's perfectly fine to send us a comment that says, "We don't like your standards." It's hard for us to action those. And so, it's much easier if we can kind of frame that in, you know, what works, what doesn't, what we got right, what we didn't, based on experience and the data that's out there in the community.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Well, just to try playing that back relative to my question about the degree of change, so then what would be helpful would be any infor—observations about the ease of changing from one standard to another in terms of the degree of change from Stage 1 to Stage 2.

Jodi Daniel – ONC – Director Office of Policy & Research
Yeah, I would say generally with comments, the—we read all the comments; we're required to—and consider all the significant comments. But as Doug is saying, if there's rationale, if there is evidence to support somebody's perspectives, if there are proposed alternatives and rationale for that and how that would work, not just for a particular organization but more widespread, that all helps us to provide information to—you know, to make changes if, in fact, that's appropriate and to consider those comments really fully. So the more robust the comment is and the information that goes along with it, the more we're able to act on them.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Great. Thank you.

David Blumenthal – Department of HHS – National Coordinator for Health IT
If I could add something there: When you think about your comments, think about a broad range of users of standards. So we're all influenced by our own experience, but there are many, many kinds of providers. Seventy-five percent of visits in the United States are to practices of five or less. So we have to be cognizant of the wide range of users of these standards. And we have broad, ambitious goals to make the American public—have the American public benefit from electronic health records that have the properties the Congress inserted into the HITPC law, and interoperability's clearly one of those. But it has to be interoperability that is available to large and small organizations and practices of many types.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Dixie, your initial comments.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Okay. First of all, as I mentioned earlier, in general, we like the approach of specifying the standards as functional requirements to allow for flexibility and adaptability in general. My first comment really is to help, I hope, influence the certification NPRM that I know is coming down the pike. Certifying privacy and security through the EHR module approach is likely to cause big problems. First of all, if every module—if every EHR module has to meet all of the security specification criteria, then it will be impossible to achieve uniform, enterprise-wide enforcement of security and privacy policy, because each module will be doing its own thing. But on the other hand, if that set of EHR modules include one or more modules that are security specific, then again, it's going to be impossible to enforce enterprise-wide enforcement of security—of privacy and security policy, because how do you make sure that all the other EHR modules are using the security services provided by those security modules? So I think that that needs some

serious rethinking—that whole approach. This is probably—will—should be thought of in terms of a lot of infrastructure-type services, but especially privacy and security.

The second comment has to do with the Cross-Enterprise User Assertion, the—or the SAML XUA standard. All of us commonly call it single sign-on. And the workgroup recommended that the XUA cross-enterprise single sign-on be considered for 2013 and not for 2011. And the reason is that, in truth, very few organizations even do single sign-on within their organization, and those standards have—rarely if ever used to achieve single sign-on between enterprises, so that's a major, major stretch. For—secondly, single si—you know, XUA and SAML are not really authentication standards; they are really single sign-on standards. And what I would rather see is that we strengthen the HIPAA securi—the authentication standard, provide a standard that addresses individual and entity authentication that's stronger than what's in HIPAA rather than stretch to the cross-enterprise assertion and single sign-on. I think we'd be better of looking at perhaps certification criteria that would require products to at least support two-factor authentication, for example, which a lot of products do. And that's far less of a stretch for products than to ask them all to support single sign-on cross-enterprises.

And my third comment is that by translating the recommended standards into functional standards, some of the standards seem to be slip—to slip through the cracks, authentication being one of them, access control being another one. Neither of those are really approached in the—addressed in the standards part. And while recognizing that the intent may have been to focus on exchanges between enterprises, there are certain dependencies that security—there are dependency—security dependencies that need to be addressed. And a great example is the single sign-on SAML XUA example. If you are going to have single sign-on between enterprises, that is directly dependable—dependent on the strength of the individual authentication and the individual enterprises. So before we leap to a cross-enterprise single sign-on, I think we should look again to strengthening the individual authentication within enterprises. Even recognizing that is an intra-enterprise standard, I think it's important to look at it, because ultimately that's going to be the weakest link in cross-enterprise exchanges.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Right. Janet, initial comments or feedback that you've had from your folks on the Interim Final Rule?

Janet Corrigan – National Quality Forum – President & CEO
The main issue that was raised with our group that you've already touched on, really, was this transition issue of going from attestation in the first year to using the PQRI XML in the second year and then to the standards in the third, so…

John Halamka – Harvard Medical School – Chief Information Officer
Great. And there will be some further detail, I'm sure, that gets explored, like some of the initial work that the NQF HITPC group has done—looked at CDA documents as the source for quality measures, for numerators and denominators. And now that CCR or CCD are allowed, at least at the moment, there isn't—wasn't a path on the quality secondary use side of getting CCR into the quality measures. It's great certainly for patient summary, and there's no question about that.

Well, Aneesh, you've joined us. Welcome and, you know, to the extent that, you know, any regulations I want you to say aloud—

Aneesh Chopra – White House – CTO
This reflects my views, like—

John Halamka – Harvard Medical School – Chief Information Officer
[Laugh] Okay. Well, I'd ask Jonathan's permission for just a couple minutes, because we started late, if we could just open it up for some other general comments and reactions. So I know, Carol, you had a comment.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

Yeah, even though I lost my tent card. Have to use my hand now.

I just wanted to make a few comments and start by commending the thoughtfulness that went into writing this rule. It's—it was very apparent to me reading it; it's more apparent to me, Doug, listening to you sort of talk about how you had to weigh some very challenging issues in trying to figure out what—you know, what ended up in the rule. And I have a greater appreciation for that listening to your comments today and just commend you and the rest of the ONC team for really being thoughtful about this.

I know that, you know, one of the boundaries you placed on that thing came from listening to you, and I completely, again, agree with this—is to bound what's really required by what meaningful use really requires, as opposed to what's nice to have—or should have, because I think this is—you know, as Dr. Blumenthal was just saying, this has to have bearing on a lot of different users, including users who are going to be using EHRs for the first time, who are in small practices where the level of support may not be as great. So I think bounding it by meaningful use is really also important.

And I also commend you for following the input that we heard on the Implementation Committee, which was that implementation is really what should drive greater specificity. And you know, it is so tempting and so seductive to really say, "Well, you know, if we really highly specify every standard, even if some of these aren't being used yet, then we'll get there quicker, but history is littered with examples of why that is never the case. We have lots of highly specified standards that have never really been adopted and never really used and have never really lived through what makes a standard a standard, which is use and change and evolution and tweaking and fixing. So I think that the discipline exercised there was very important—and leaving room for that especially, as I heard you say today, in areas where they may not be health-specific standards, especially in the sort of transport realm.

So I think all of those things came through from your comments today, and certainly in the way the rule was written. Obviously we'll all have little niggly things, and many of them have been raised here today: QRDA, LOINC, et cetera. But on balance, I think the gestalt of the approach has been very sympathetic to a lot of the input that the Implementation Workgroup heard, and I just appreciate the challenges you had to weigh in getting this out the door in the time frame that you did, so congratulations.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Stan.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Oh, I think we're ahead of [indiscernible].

Jonathan Perlin – Hospital Corporation of America – CMO & President
Okay, well…

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
I'm happy to jump in. I wanted to follow on with one thing, though: The—I think Wes was—said or hinted at, but—it would be wonderful if we could think of a new approach that, at any given time, would specify what's expected in terms of explicit interoperability, whether that's a combination of, you know, a particular version of HL7 or of CDA plus, you know, a guideline and not—recognizing some mechanism that allows that to change over time so that we're not, as you said, ossified. And I just tried to think of creative ways that we could do that, and I don't—if I had a good solution, I would put it forward. But maybe one step in that direction would be establishing, not by law or by regulation but—a center where somebody could ask or submit a message and say, "Is this message conformant?" And the conformance center would probably make some arbitrary decisions, but that might carry some weight in the marketplace so that people could say, "My message, you know, is conformant according to NIST or according to"—so I don't know if that's a solution, but I'm trying to—because we really would like, at any point in time, to know explicitly how we could create interoperability and, at the same time, have the flexibility to have that thoughtfully change from time to time without having to go through the full weight of the regulatory process.

John Halamka – Harvard Medical School – Chief Information Officer
And one assumes NIST and the certification rule will address this issue of ensuring that there is conformance testing and tools. And the challenge—you know, when I think about this, if you have a USB device and you plug it into your Macintosh or to your PC, it isn't there are 17 different flavors of USB and you have to tweak them; you're pretty much convinced that the USB device will work. Well, I mean, Carol, you outlined this tension extraordinarily well. The IFR isn't a USB device for health care yet [laugh]. It'd be great.

And so the question really, I think, to all of us that we'll work on in our comment period—and I'm sure we'll look at Stages 1, 2, 3, and 4 and 5—is, just how specific can you get so that the industry can, and the small doctor's office can, adapt to whatever the requirement is, getting us as close to plug-and-play over many years as we can be? I mean, I absolutely understand that 10 years ago, it was $10,000 an interface; and Stage 1, it'll be $1,000 an interface; by Stage 2, $500 an interface—you know, we'll get better and better over time, and that balance of specificity and flexibility for innovation is one that will constantly have attention in this Committee, I'm sure.

Cris.

Cris Ross – MinuteClinic – CIO
Thank you. I want to join my colleagues in commending you on what was no doubt very difficult work and coming up with, again, thoughtful decisions. I recognize that balances and compromises that need to be taken into consideration—as a hardcore vocabulary person, I want to particularly commend you on some of the stances you took with vocabulary, specifically a less ambiguous specification of medication and laboratory data; that was, I think, welcome.

However, in a similar vein, the issue of tightening or clarifying what people want to know seemed to take a step back in the exchange data. I know this is going to be a controversial issue, and there are emotions on both sides, but when we are confronted as a provider with supporting both CCD and CCR, we are confronted with essentially least-common-denominator capability. And if you think of the goals of secondary data use, which we do a lot, particularly as it's involved in decision support, as it's involved in quality, safety, and quite shamelessly research to understand outcomes and effectiveness, having that kind of least-common-denominator specification could erode the specificity and, frankly, the utility of the information that we would be managing. We're confronted with a requirement of taking—of saying we want to populate, for example, our personal health record with CCD content; and yet, when we're confronted with underspecified content that comes through CCR, we're going to be confronted with awkward decisions about "Well, what do we do with this?" because it doesn't have the detail, the substance, or the specificity to enable and optimize the kind of information that we seek. I won't go on about that—I think we're all familiar with these issues—but it does pose a difficult option for us.
The final comment is, I was surprised there were no Stage 3 recommendations. I understand you're trying not to ossify a regulation and you're trying to let the market evolve; on the other hand, in this marketplace, 4 years is a very short time. And given the lead time and, if you will, the compass settings that could arise from clarity about what a Stage 3 direction would look like—for example, in the patient problem list, I think the HIT recommendation had been "Let's do SNOMED. It's got the granularity; it has the specificity; it's where we want to go." Yet there's no mention of that in what was ultimately published. It's still this kind of "Well, ICD10 or SNOMED, take your pick." And we're left again with the least-common-denominator kind of issue. And if the HIT infrastructure is indeed to become a circulatory system rather than a—rather than have a puddle that we splash in, a well-engineered circulatory system would be desirable. Having clarity about what those specifications might be, I think, would be welcome.

Jonathan Perlin – Hospital Corporation of America – CMO & President
[Indiscernible] say, I think—in the spirit of my own introductory comments, I think you've really teed up some of the things that require additional work in the agenda for this Committee. I mean, it's interesting, because we've danced around the CCR/CCD discussion, and then, you know, rather than a framing of the least common denominator, I see similar utilities and different utilities. Clearly in the patient care summary, there is a broader overlap than in some of the architecture around the quality reporting, and I think we're going to need to have coherence at the framework. Now, putting that back together with

Stan's comments, which I think were, you know, just extremely helpful, when we're forward looking and trying to provide a continuity path for all the different entities that will use the standard.

So we really need to make sure that we deliver not only the initial best of breed but really nothing less than, if you will, a harmonization factoring so that things are really forward compatible. And so, I think there's a way to start with some degree of specificity—some degree of noticeable absences, you know, at the same time having a real context that leads to clarity in terms of the 4- or 5-year path. But that's really our next body of work—is that there are certain areas that can tolerate some ambiguity and other areas that probably need a clear signal.

That—notwithstanding that, your point is absolutely correct that the lead time is very short. Four years is really unthinkably short.

John Halamka – Harvard Medical School – Chief Information Officer
One last comment and then we'll turn it over to Jonathan and Karen's presentation. So Wes.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Thanks. Just—I have been called Debbie Doom in this forum before, but—so let me be funny today [laugh]. When I think about all of this, I think there's one fundamental difference to what I remember—everything we ever tried to do on standards, which is, we actually think we're on the cusp of standardizing codes. For 30 years in interoperability, that has been the impossible thing that always left the rest of it to be details. I mean, you know, why worry about the exact format if you can't standardize the code, right? We're on the cusp; we still have major lab sources that still have 18 different sets of codes coming from their own internal places. We have learned in testimony to the Policy Committee about the number of different lab sources there are. But fundamentally, that is simply the recognition that we can get to standardize codes. And I particularly commend the work of HITSP and Regenstrief in terms of identifying a subset of LOINC that's necessary in that regard. That is the biggest game changer in my entire history of standards, so I'm delighted about that.

This leads to a question which—you may very well say, "Ah, you've got to wait for the certification reg," but it's good to ask the question now anyways. The—as I understand it, in order—I guess I don't know which reg this is now. There is going to be—there are standards that we have in the IFR. There is a—those are understood somehow to be part of a cri—of a certification criterion for a process we don't know yet. But it is the case that I could achieve the meaningful use criterion without following the standard, right? So if I was an EHR vendor and my—if I was a user of a given EHR and my vendor is willing to import in all of the 18 different sets of codes, I could meet the meaningful use requirement. The vendor would've been certified to support the standard approach, but—is that correct?

Jodi Daniel – ONC – Director Office of Policy & Research
So I think I understand what you're asking. Let me try to repeat it back, and tell me if I've got it. The standards and certification criteria must be in the product in order for the product to be certified, and the eligible provider or hospital must be using a certified EHR technology to qualify for the incentives. That being said, it is possible—and Karen may—I don't know if you want to comment on this at all or not—it may be possible to meet meaningful use without using a particular standard or without using a particular standard in every instance. So there's a difference between what is required for the technical capabilities and what is required for implementation and for use of that technology. Those are two different sets of requirements.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Thanks.

Jodi Daniel – ONC – Director Office of Policy & Research
Does that address your question?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I think so.

Jodi Daniel – ONC – Director Office of Policy & Research
Okay.

John Halamka – Harvard Medical School – Chief Information Officer
Well, I think we've teed up today a number of the issues in the IFR. So the feedback, I think, David and Doug, is overwhelmingly "Thank you" and positive and "very well done in a very short time," so… [Applause] But there's polish to come, and we will be getting our comments to you in a timely way through the process I outlined in our next meeting on February 24 here—will be to review the comments the workgroups have made. So thanks, everybody, and on to Jonathan and the NPRM.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Well, how nice to make that transition on such a note of optimism. And indeed [laugh], if there is no holiday in ONC, I don't think there's much downtime at CMS. And I really appreciate Karen Trudel walking through the companion set of rulemaking, which is the Notice of Proposed Rulemaking for the electronic health record, the meaningful use criteria. And so, Karen, look forward to your walking through this area. Certainly it's something that has been garnering a good bit of discussion, and look forward to your taking us through the definitive interpretation.

Karen Trudel – CMS – Deputy Director, Office E-Health Standards & Services
Thank you. Okay, just as an additional reiteration of the overview, the Notice of Proposed Rulemaking that defines meaningful use and sets out all of the various requirements for the Medicare and Medicaid incentives programs was also published on December 30; on display, published on January 13; and the comment period, again, closes at the same time on March 15.

I think Doug went through this a good bit in talking about what is in the IFR—what is in the CMS EHR incentives program NPRM is the definition of meaningful use; the discussion of hospital-based eligible professional, which is an interesting issue; the requirements for the Medicare fee-for-service; Medicare Advantage; Medicaid; EHR incentives programs; and the normal information collection and regulatory impact analysis. What's not in this NPRM is any information about ONC grants; the changes to HIPAA that are related to security and privacy; obviously the initial set of standards and certification criteria, which are in the IFC; and the proposed regulation that will establish the certification process, which we're all still looking forward to.

So what we tried to do—I think Doug has talked about a lot of the challenges and balancing acts that ONC went through in developing the standards. And we had a certain amount of balancing as well, because we're dealing with three different programs here: Medicare fee-for-service, Medicare Advantage, and Medicaid. We have always to deal with the flexibility for the States with respect to Medicaid and the fact that many of the States are really leaders in the area of health information technology. We wanted to recognize that while still trying to be as consistent as possible across the three programs to make sure that hospitals and eligible professionals who are trying to figure out which or how many of the programs they wish to participate in will not be faced with a number of disparate requirements. We're also obviously trying to closely link with the ONC standards and certification processes. We're building very heavily on the recommendations of the HIT Policy Committee. We're also trying to coordinate with existing CMS quality initiatives, including PQRI. And we're also dealing with the notion of the staged implementation that will help us move through the various stages to get to an ultimate place where we've got health information technology that is actually driving quality and outcomes.

So with respect to the definition of meaningful use, the statute requires that it includes quality reporting, electronic prescribing, and information exchange. And you're all well aware of the process that we went through to define meaningful use. We started last April with hearings for the National Committee on Vital and Health Statistics; many discussions with respect to the HIT Policy Committee and the Standards Committee; many listening sessions; and then an extremely robust discussion, dialog, and review process through the HHS review process and also with OMB. And one of the things that I think we added to the considerations at that point was an increased understanding, I think, of how to factor Medicaid into

some of these discussions. When we began talking about some of our meaningful use criteria, people would say, "Well, is that going to work with dentists? Is that going to work with nurse-midwives? Is that going to work in the pediatric space?" And so, we really did have to broaden some of our thinking and try to make sure that we were indeed doing due diligence across the three programs.

So I'm sure you've seen this slide before: the conceptual approach to meaningful use. We're starting with the data capture and sharing, moving on to advanced clinical processes, and then leading to the ultimate goal of the improved outcomes. And we're defining meaningful use in stages through rulemaking. Stage 1 is what you see in this NPRM. These are the requirements for 2011. We will do additional regulation for Stage 2 and for Stage 3, and that will be informed by the deliberations—ongoing deliberations of the Policy and Standards Committees and also the input that we get back with respect to how the uptake is working in 2011—how EPs and hospitals are actually responding to the regulations and telling us whether they think that they're ready to move on.

So we coordinated, I think, and displayed the meaningful use criteria in terms of the health outcome priorities that were developed from the National Priorities Partnership. And we've used that as the format and the structure for the regulation. So we're talking about improving quality, engaging patients and families, improving population health, and privacy and security protections.

Rather than requiring that eligible professionals and hospitals who are not adopting in the first year jump on board to later in higher sets of requirements, we've come up with a stairstep approach, whereas a provider who implements in 2011 will be required to apply with the stage one criteria. Someone who jumps onboard for the first time in 2012 will also stay with the stage one criteria. In 2013, if you have already adopted, you move on to stage two. Someone coming in at the beginning in 2013 for their first year can still comply with stage one. We're trying to make sure that we don't have the train accelerating so quickly that only the people who've adopted at the very beginning will ever be able to jump onboard. So eventually we get to 2015 and later. Everyone will have to evolve to stage three so that we can be consistent because that's the year that the disincentives take over.

With respect to the meaningful use criteria, we have 25 objectives and measures. Some of them are yes/no answers. Some of them will require a numerator and a denominator, and we'll talk a little bit later about the fact that we will be, at least in the beginning, relying on attestation, which I want to make very sure that….

Unidentified Man
Hello?

John Halamka – Harvard Medical School – Chief Information Officer
Yes, we can hear you.

Unidentified Man
Okay. Well, no one was answering.

John Halamka – Harvard Medical School – Chief Information Officer
That's because it's live. Please go ahead put your phone on mute.

Unidentified Man
Okay. Well, I was checking to see if it was working. Thank you very much.

Karen Trudel – CMS – Deputy Director, Office E-Health Standards & Services
…and we're already working on an audit program that will go on behind the scenes where we will go out and validate some of the responses. So we have 25 objectives and measures for eligible professions and

23 for eligible hospitals and critical access hospitals. Ten of those measures require yes/no, and 13 require a numerator and denominator.

We've proposed a reporting period of 90 days for the first year. And the reason that we've done this is, again, to give people as much time in that year as possible to adopt, to get up to speed, and to be able to demonstrate meaningful use. We're hoping this will allow for maximum uptake for the first year. In subsequent years, we would require the full year as the reporting period. And we are soliciting comments on that point.

In addition to the meaningful use criteria, we are also proposing a number of clinical quality measures, and there's some confusion about this because reporting clinical quality measures is actually one of the meaningful use criteria, so imagine this as sort of a drilldown to that one criterion. In 2011, again, we will have providers submitting summary quality measure data to us by attestation partly because we believe that we won't be ready to accept it electronically, and partly because we don't feel that the vendors and providers will actually be able to compute the measures from their EHRs and have good vehicles with which to submit that data to us. So we're again trying to ramp this up gradually. In 2012 though, we do believe that CMS will be ready to receive electronically submitted data, and we believe also, and part of our planning is that for quite a while, we will have to be able to accept that input from a number of different sources, whether it's NHIE, a registry, or some mechanism that we set up directly.

The EPs are required to submit clinical data on two measure groups, and this is a distinction because initially we weren't establishing criteria and quality measures by specialty. As a result of the dialog that went on through the review process, we decided to separate out the clinical measures into core measures that were appropriate for all providers to report, and specialty measures, and the eligible professional will need to select which specialty they wish to be associated with and will then stick to that specialty, as they report for year-to-year. So eligible hospitals will be required to support, to report summary quality measures on all of the requirements that are applicable to them.

The core quality measures for EPs, and again, we've specifically requested comments and input on this during the comment process, preventative care and screening … regarding tobacco use, blood pressure management, and drugs to be avoided by the elderly. And it's important to note that these requirements are only with respect to patients for which the measure is appropriate. A pediatrician certainly is not going to be reporting especially on that third measure. The specialty measures, the specialty groups are listed here. Again, the eligible professional will self-select, and it would be with respect to probably the largest subset of their patient population for which these measures are appropriate. If we were to establish measures for every specialty and subspecialty, the complexity of the process would, I think, have probably been unworkable.

Hospitals will be required to report on all 43 clinical quality measures. Hospitals that are only eligible for Medicaid will report directly to the states, and for hospitals where the measures don't apply, they'll have the option of selecting alternative Medicaid clinical quality measures. Some notable differences: One is that in Medicare, the Feds will implement. It's a national program. For Medicaid, it is voluntary for the states to implement. A state may choose not to participate in the incentives program. In Medicare, there will be fee schedule reductions beginning in 2015, so we have disincentives in 2015 for Medicare for those that do not meet the criteria of meaningful use. There are no reductions in payment amounts in Medicaid.

Under Medicare, the provider must be a meaningful user in year one. For Medicaid, there's a statutory requirement that they may receive an incentive payment simply for adopting, implementing, and upgrading EHR technology. The maximum amount for Medicare is $44,000 for an eligible professional.

For Medicaid, it's $63,750, which would leave one to believe that for the eligible professionals who could select one over the other, Medicaid would be the selection that they would likely make.

The meaningful use definition will be common for Medicare, but we will allow the states to build on top of it, so think of Medicare meaningful use criteria as the floor, and states that desire to do so can apply to adopt more rigorous requirements. The last year an eligible professional can start under Medicare is 2014. The last payment in the program is 2016. Under Medicaid, the process goes on for a good bit longer. The last year they can start is 2016. Payments will go through 2021.

There are some changes from the HIT Policy Committee recommendations, and I won't go into these in great detail. Some of them, for example, the recording advanced directives, documenting the progress notes, there were reasons to reduce, to delete those with respect to advanced directives. It just didn't appear to be appropriate necessarily for all patient populations and all practitioners, for example. We have made some changes to the requirements. We've increased the clinical decision support rules that are required from one to five. We've removed, where possible, from insurance eligible checks because that's already a HIPAA requirement that all plans are expected to be able to support already, and I won't go into all these detailed changes either.

The timeline is that Medicare can begin to pay incentives to eligible professionals in January 2011. We are pushing as hard as we can to be able to make payments early in 2011. Medicare can pay eligible hospitals and critical access hospitals no sooner than October 2010. Again, I would remind you that there's that three-month reporting period that would have to start after those dates, so that beginning in January 2011, an eligible professional could begin to display meaningful use in that 90-day period and then the payment would be made after that time. And Medicaid eligible professionals can receive payments as early as 2010 for the adopting, implementing, or upgrading of EHR technology.

The next step to this process are to receive input from the policy and standards committee. Our public comment process ends on March 15th. Someone mentioned when it would be possible for the committee members to see the comments. It's our long-held experience that 95% of the comments come in on the last two days, so it will be a while before we can work our way through them, especially since we are expecting a fairly large volume of comments. My regulation team that's sitting back at CMS and is going to be looking at these comments, implores me to mention every time I speak that the regulations.gov Web page is the absolute best way to submit comments. They're electronic. It's a lot easier for us to deal with them. We get them faster, and it just works better all the way around. We will go through the same CMS, HHS, OMB clearance process that we did before the final rule is anticipated to be published in the late spring.

I'd like to talk a little bit about the public comment process, and many of you may be aware of this already, but as was mentioned by Doug and Jodi, the more specific the comments are, the easier it is for us to make them actionable. We need to be able to make any changes that we make be a logical outgrowth of what we already published, and it's very helpful for us to be able to draw a logical path between what we published, the comments, and what we're going to put into the final rule. There are a number of places where we solicited comments. Comment is welcome on anything. But the clearer and more specific the commenters can be, the better. As an example, with respect to meaningful use criteria, a comment could be, "I like this criterion, but I think you should tweak it a little." Or, "I like this criterion, but I don't like the reporting requirement that goes along with it." Or, "I like this criterion, but not for 2011. I'd rather see it in 2013." Or, "I don't like this criterion at all. I wish you'd take it out." Or, "There's something that you missed, and this is what it is and where it should go."

So those are the kinds of things that we're really hoping to see, and it's going to be a very challenging process to weigh all of these comments. There are people who are very passionate about moving the bar as high as possible to really jumpstart this whole movement, and others who are saying, if you set the bar too high, no one will come to the race, and you will not have accomplished anything. And it's a very difficult balancing act that we're going through to try to make sure that we set the balance in the right place and that we don't inadvertently leave either large or small constituencies behind in the process, so I'd be glad to take your questions now.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thank you very much for a terrific overview. I think everyone who is watching these deliberations for the public process is appreciative of the desire to set the bar high for progress, not so high that it's insurmountable. But behind that, there are a lot of moving parts, and you alluded to some of those. In fact, in the attestation process for the stage one, it really ties to the earlier discussion of the IFR. Are the quality measures, for example, the product of one certified system or a derivative of multiple certified systems, or in fact a combination of certified and potentially uncertified components that provide the granularity. I would hope that in our discussions today, particularly as it relates to the standards, that we provide these words of specificity that's helpful to you, and is representative of the sort of questions that I believe I'm hearing from our multiple constituencies. Thank you for that overview, and number of flags already up, and we'll go around the room starting with Janet Corrigan.

Janet Corrigan – National Quality Forum – President & CEO
Thanks, Jon. Karen, this was really very, very helpful, and I just applaud you and your staff and others. This was a huge amount of work, and it's also just incredibly refreshing to see such close collaboration between CMS and ONC and the various programs at HHS. And I think it's clear you've achieved a degree of very significant harmonization of quality requirements across the different programs, whether it's public reporting or P4P or the meaningful use criteria, which is clearly really needed in terms of minimizing burden and sending clear signals to the field.

I like your conceptual approach slide very much that first talks about the data capture, then moving to advanced clinical processes and really improved outcomes. One of the things that's clear though from the list of measures in the various tables that are included in the proposed rule is that the numbers of measures are greater than what were recommended through the policy committee and the standards committee. Essentially what it consists of is just about all or most of the measures that are currently being used for the voluntary reporting program and hospital compare. So we have a lot of measures.

Given that that's – and I understand why we are where we are. You wanted to have a greater breadth of coverage for different types of specialists that would be participating in the program. I think it's going to be really important though going forward, the way that this is, the messaging around this and the communication. And we need to make the case that this set of measures that we're going to begin with data capture is actually going to be related to some very significant improved outcomes down the road. And I think you can make that case. We know that many, not all of these measures, but many are grounded in the national priorities and, in those cases, there are some very clear evidence base about what we expect the outcomes to be, but we need to capture that and communicate it.

Then there are many examples here, whether it's healthcare acquired infections or it's prophylaxis for VTE. We know from the CDC estimates the number of patients who die from VTE and could readily communicate how some of those measures that we're incorporating now will lead to better outcomes down the road. And I think that's really important for two reasons. First, that there's a real backlash from the field in the quality community, you know, why are we measuring what we're measuring? Are these really the important things? I also think it's important to communicate to the American public, what are

you going to get out of all this, all these dollars that are spent, in some very tangible ways that they can understand what those outcomes are.

The third, I think if we look at those measures through that lens, we're probably going to find that some of these measures aren't the most important. They've come to us through processes. This is essentially taking the measurement, the measures that we have now and hardwiring them into meaningful use, so we are going to probably find that some of them, if we started with a clean slate, they might not be the ones that we would pick today as most important for outcomes we want to achieve in three, four, five years down the road.

And so, I think we need to go through it, and look at it through that lens, develop a succinct communication plan that really says where we know these measures are important to achieve these specific outcomes and try to quantify in any way we can within a range in some way. But I also think it's important to really think about the plan for moving to an even better set of measures, as this evolves, as we go forward. And, as you know, the timeframe for measure development and endorsement is a couple of years, and it doesn't happen overnight.

Have you started to give thought to how the measure set can evolve operationally and what we need to be doing now to make sure that that does happen over the next couple of years, so we get the greatest outcome improvements from this effort?

Karen Trudel – CMS – Deputy Director, Office E-Health Standards & Services
I think you raise a number of good points, Janet. I would say that of all the parts of this regulation that I've been really immersed in, the quality measures is probably the least, but I would say a couple of things. What we're trying to do is to build a good, solid base in 2011 to take off from. And you're absolutely right. There are a lot more measures in here than there were before. What we were trying to do was to be inclusive and get measures on the table, and get everybody thinking about them and talking about, not excluding specialties and so many people who would say, I can't see myself in here at all. So I think there's going to have to be in the comment process, and what we're hoping for is that there's a real refinement of the measures that we're proposing for 2011.

And if some of these measures aren't well enough linked to an outcome, or if for instance we put a measure in there that has already pretty much topped out in that, yes, it's a good measure, but the industry as a whole has already turned their attention to it and made so much progress that it's not worth measuring it anymore. We definitely need to know that. We did try to avoid that where we could, and there were lots of, as David can attest, very robust discussions on this particular issue, as we even went through the last days of the review process.

I think this is something where we very definitely need lots of public input. Again, is this measure the right one? Is it right for 2011? Is there something we missed? Is there something that should come out? And then, as far as moving onto the later, how do we morph this into 2012, 2013, etc. I know enough to know that there are a lot of moving parts to the quality measures process, lots of players, and so I think that's a dialog that is more than a dialog. It's an open discussion that needs to happen, and I think that CMS and ONC need to engage in that.

Janet Corrigan – National Quality Forum – President & CEO
Thank you. Once again, kudos for what you've done. I think it's really….

Karen Trudel – CMS – Deputy Director, Office E-Health Standards & Services
Thank you.

David Blumenthal – Department of HHS – National Coordinator for Health IT
If I can … comment, thank you, Janet, for all the work you do and the NQF does and all the work you did on the committee. The process of drafting this regulation was deeply informed by not only the standards committee work, but also the NQF work. The process of regulating, I've learned, is that if you include a reference to something in the regulation, you can take it out, or you can modify it, but you can add it if you haven't included it, so we couldn't add in any quality measure.

If someone said to us, well, you know, you have a list of measures for cardiologists, but you didn't include the one that really matters, we kind of go, oh my, God. We don't have it in there. But, you know what? We can't add it because it wasn't there for comment. So if there are some measures here that anyone in this panel or anyone listening in from the public thinks really don't add or don't have the potential to improve outcomes if they're tracked and we try to affect them over time, we really need to hear that from you, and they can be dropped, and nothing would make us happier than to simplify the regulatory burden associated with complying with meaningful use. We can't add anything. We can't add new measures for which there's no reference, but we certainly can change things that are in there to make them better, and we can also drop things that are invaluable.

Janet Corrigan – National Quality Forum – President & CEO
Is it correct that comments about, gee, I wish you had included this measure, might be very helpful for 2013 and 2015?

Karen Trudel – CMS – Deputy Director, Office E-Health Standards & Services
Absolutely.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Yes.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks. We'll go to Walter Suarez.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Yes. Thanks. Hello, Karen. I, like everyone else, I commend you and Tony and the whole team for just an incredible set of regulations. I have two questions, I guess. The first one is about Medicaid and the degree to which there's flexibility in the regulations for a state and state agencies to expand or to modify some of these meaningful use requirements. If you can talk to that, and perhaps even give a sense of whether CMS is working to provide some guidance to Medicaid agencies around that. So the degree to which Medicaid agencies have flexibility and state agencies and states, in general, flexibility to, again, modify or contract or expand and to what degree CMS is actually working on developing some guidance for Medicaid agencies around that.

Karen Trudel – CMS – Deputy Director, Office E-Health Standards & Services
First of all, as I said, the requirements that we've put out are proposed to be a foundation that will cross Medicare and Medicaid, and that we acknowledge that the states can add on top. So we're hoping that states that really want to take themselves to the next level can do that, but we don't want to have a foundation that's a little bit different in every state. That's going to be too difficult to implement and too difficult for providers to understand if the Medicare requirements are the same federally, but the Medicaid requirements are all slightly different. We have made provisions for that, and we will see what we get in from the comment period from states specifically.

The other thing we have done is to provide states with some advanced funding to come up with a plan that would cover both their implementation of the Medicaid incentives program and also some other aspects of their health information technology environment, and they're developing, each one is developing a plan and submitting it to CMS. As we get those plans, we will have a better idea, I think, of what the states are thinking about, and our Center for Medicaid and state operation is also having a series of calls with states to go over the regulations and discuss a variety of issues. So we're definitely in contact with the states and trying to get a sense of where they want to be.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
I guess the second question, and this probably involves … as well. I think there's a lot of confusion out there, and I have seen that in various venues too. And perhaps these happen because of the coincident of release of both an NPRM and an IFR. The sense of the comments and the ability to comment and the degree of flexibility that each of the two agencies have to handle those comments, and certainly the relationship that exists between the IFR setting the standards and the meaningful use NPRM then using them to establish the stages for measuring that.

I know this also was covered partly, I guess, at the policy committee I was listening to. But could there be some clarification about the IFR and to what extent there aren't going to be possibilities of modifications to it? I know the NPRM, of course, is everything pretty much is open. I know Jodi probably has a better perspective on that too.

Karen Trudel – CMS – Deputy Director, Office E-Health Standards & Services
Walter, you raise a really good point, and that's the very reason why we decided that it was so advantageous to publish both of these documents on the same day because we wanted to the public to be able to see them both at the same time, and to have that information when they make their comments. So I expect Jodi and I will be having many discussions about the comments she received and the comments we received, and there will be lots of opportunity for us to make sure that we're each informing the other's processes. Do you want to add anything, Jodi?

Jodi Daniel – ONC – Director Office of Policy & Research
Yes. The only thing I would add, and this is something I had said at the policy committee is that it is an interim. It is a final rule. It does take legal effect, unlike the proposed rule. But it is interim, and there's a reason that we have that word. We are accepting comment on the rule, and we do expect to consider … comments and make any changes that are necessary, and to work closely with CMS to make sure that our rules are aligned.

That being said, it does in fact have the effect of law, you know, on the effective date of the rule, which should be 30 days after publication. And so we're aware of that, and that may impact how we consider the comments because we know some people will start acting on them, given that they are law, and that will weigh into our thinking in considering the comments and in how difficult it would be to change those requirements and for folks that are trying to implement those requirements, so it's a balance. We'll be looking at the comments in light of the fact that it is an interim final rule. We will be considering comments.

We will make – I expect we will make changes to reflect those comments. Then we'll work with CMS closely to make sure that the rules are aligned. We're not going to leave the IFR as it is, and CMS go down a completely different road, and then the rules don't synch up. We've very much concerned about making sure that they fit well together.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO

Generally speaking, there could be one of three things that could happen to each of the certification and standards. One is add new ones. The second is eliminate ones that were published, and the third is modified with constraints or expansions, the ones that were published. Are there any restrictions, given that this is a final rule, as to whether new ones can be added, existing ones can be deleted or eliminated, and constraints around modifications to the ones published?

Karen Trudel – CMS – Deputy Director, Office E-Health Standards & Services
Let me reiterate a point that I made and that David made much better because his point was in plain English, and mine wasn't. For a final rule, you can't add things to it that aren't what our attorneys call a logical outgrowth of what we already proposed. You can't come up with something absolutely new because no one will have had a chance to comment on it. What we're primarily looking at is changes that we can refer back somehow to the proposed rule and deletions. So I think I'm intuiting that your concern is that if we added a new meaningful use criterion for which there was no standard, how would the certification process handle that. And it's very unlikely to happen.

Jodi Daniel – ONC – Director Office of Policy & Research
To also clarify, everything Karen said, I agree with. Whether it's an NPRM or an interim final rule with comment, the same rules apply as far as whether or not you could add something … and that we would have a problem doing that, so it's not dependent on whether it's a proposed rule or a final rule. The legal limitation applies either way.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
So there are comments, significant comments to add the following standard to the IFR, and there is evidence that there will be clearly benefits, there is no restriction to adding back – I shouldn't say adding back. Adding a new standard into the stage one IFR.

Karen Trudel – CMS – Deputy Director, Office E-Health Standards & Services
If we didn't provide any discussion of it in our interim final regulation, if it wasn't mentioned anywhere, it's not in our preamble, it's not in our reg text, and somebody comes up with this great idea for a new standard, we would not be able to go directly to a final rule with that. We would have a legal problem with doing that. We would have to put it out for comment again before we could adopt it so that people had an opportunity to weigh in before we created a new requirement.

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
Thanks.

Jonathan Perlin – Hospital Corporation of America – CMO & President
To put it in plain English, this may be totally wrong, but I've tried to describe the interim final rule as a what I call almost a final draft of a document, and the NPRM is kind of a rough draft of a document. This is not to suggest that the work on either was any different in completeness, but final drafts get polished, whereas rough drafts may, because you asked for so much comment, I wouldn't say get a lot added to it, but could be revised. In your view of these two documents, the sense that one is more final than the other?

Jodi Daniel – ONC – Director Office of Policy & Research
Legally, the IFR is final. I mean, it takes legal effect 30 days after the publication of the rule, so it does have a different weight. It is in fact law 30 days after it's published. In that sense, yes, it does have a different flavor to it. I would say, as far as the amount of work that went into it, they both received an incredible amount of work, and an incredible amount of effort, and I wouldn't say that there was any less that went into one versus the other.

Karen Trudel – CMS – Deputy Director, Office E-Health Standards & Services
But I would add that people should not think that the IFR is a done deal even though it is a final….

Jodi Daniel – ONC – Director Office of Policy & Research
That is correct.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Sure. I think the point that's been made is that I wouldn't expect radical change in the IFR. I would expect polish. I mean, is that, or do you expect? I mean….

David Blumenthal – Department of HHS – National Coordinator for Health IT
We want to get it right, as right as possible, within the constraints of the Administrative Procedure Act. The Congress instructed us to make the standards and interoperability, the standards and certification reg suggested that it be issued in an interim final form. We could have done it in NPRM. I think that I would not hold back any comments because you would think they are irrelevant. As long as there's some reference, you know, if you tell us you want to make a basketball hoop larger and like us to regulate on that, we don't have anything to hook that to in this regulation. But if it's within the scope of the regulation, we want to hear about it, and we'll try to get it right.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thank you. We've either exhausted all immediate comments or in desperate need of a biological break, and maybe the latter. I want to thank you. The process is one that's not well understood publicly or even necessarily in those who work with reasonable proximity to the process, so appreciate that discussion about how it evolves.

I think there's one area that we didn't comment on, and that's, you know, as postential end users of meaningful use, that there's a differentiation between what ultimately is regulated in the process and what is practical in terms of workflow. For example, I know that … spoke about some of differences between what came in and what was published. I think someone phrased it very well to me is that functionally it's not a ceiling. It's a floor, and in terms of those who seek to implement the order entry, I know for example in the context I work with, having as much information, including documentation approximate, is something that may make that workflow easier. So I would say that while we offer implementation guidance and those sorts of things, that we're probably also going to be faced with a number of questions that have to do with workflow, and that is something that overlaps, but is not entirely specified by this process. Just an observation there.

Along those lines, when we come back from our lunch break, and we'll take an hour for that break, we have a lot of work in terms of all of this morning's discussion, what we laid out at the very beginning is that we have initiated this discussion between the recommendations and the IFR and the Office of the National Coordinator … and we've had a number of discussions about the evolution of standards. Some of the tension between specification and over-specification and under-specification, and is there a forward path that allows a more holistic approach to continue to develop harmonized activities?

The meaningful use notice of proposed rulemaking really does reinforce that there is a finite timeline, and so I want to acknowledge that we've been joined by Aneesh Chopra and, of course, your group has been working on the implementation guidance. This is really where the standards and meaningful use criteria will have to gain life. Simultaneously, this work doesn't go on in the context, and maybe, David, as we open that up, you might offer some comments on how you see some of the grants and activities coming

out of ONC really providing signals and learning that we can attend to in terms of advancing standards and support of, as you described it in your paper, the lifeblood.

Then, quite frankly, there still are unresolved specific issues that need further development. We've talked about some of those, particularly as it relates to clarity on the go-forward: CCD, CCR, the ICD, SNOMED, etc. And look forward to really evolving from that set of discussions.

Here in Washington, it's 12:10. Let's come back at 1:10 and pick up with that discussion.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Great. Thank you.

Judy Sparrow – Office of the National Coordinator
We're ready to begin now, if you could please take your seats. The committee will reconvene, and I'll turn it over to Dr. Perlin.

Jonathan Perlin – Hospital Corporation of America – CMO & President
All right. Let's, everyone, take their seats again, and thank you very much for being back promptly. What a terrific morning. A lot of progress, and I want to take this moment to just share the number one comment in terms of frequency that I heard over at the break. This goes to the Office of the National Coordinator. A number of people, both on the standards committee and in the audience came up and said, you know, I think one of the most remarkable things is not just the quantity of work that was done, but the quality of work. And there was to the person … segment on the caliber of the work put forward by the Office of the National Coordinator. So on behalf of all of us who enjoy and appreciate the opportunity to work with you, what makes it so much fun and easier and hopefully successful is to work with such a talented team. David, just want to acknowledge not just your leadership, but the incredible staff work that was part of getting that document out timely. A couple members of the committee said that they really polished some of the ideas that were transmitted to a much more digestible and synthesized form, so many thanks.

A segue to the next body of work, the forward work, we'll go sequentially: clinical operations, clinical quality, privacy and security, and other comments in our forward agenda. Appreciate David Blumenthal going through some of the grants programs. There have been quite a number. In fact, again, I draw your attention to the *New England Journal* article, but I think it would be helpful for some comment and perspective, David, as we think about what we might learn from those programs simultaneously with our go-forward activity.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Thank you, Jon. I also want to say that the staff at the ONC and also our colleagues at CMS did spectacular work, and that this was truly a team effort. All the work we've done has been a team effort, drawing on people throughout the government, and also comments and advice from this committee and other committees, and from the public.

We had the responsibility to implement a very broad, ambitious agenda that was laid out by the Congress a little less than a year ago in the stimulus legislation, February 17, 2009. We're coming up on the one-year anniversary. The goal of that was not to produce regulations or grant programs, but to promote the creation of a nationwide, interoperable, private and secure, electronic, health information system.

That, of course, is a prodigious undertaking, even in a small country. We are not a small country. Fortunately, the Congress gave us some very helpful direction and some resources. They didn't define

meaningful use, but outlined it as a key concept, said we should do the interim final rule, which is out for comment now. Said we should create a certification process, and then allocated $2 billion to our office for help with promoting the agenda they had laid out. I don't know that they ever conceptualized this in any rigorous form, but there is a model, I think, and a change model implicit in the authorities they gave us, and that change model involves a lot of work helping providers and patients adopt electronic health records and learn to exchange information and learn to use that information for improved clinical decision making over time.

There is a foundation to this work that they highlighted for us and that has taken the form of a series of grant programs. One is helping, especially less well-resourced providers of care, to become meaningful users, and they pointed us toward a program called the regional extension center program, which we have adopted as a way of providing guidance, technical assistance, support and advice, and information and knowledge for program and office and workflow redesign in hospitals, primary care, and other physician offices and nursing settings as well. So we've, as a perspective article, we've put $643 million into creating up to 70 of those centers.

The Congress also directed us toward using the states and state designated entities as a way of encouraging exchange of information, and we have invested $560 million in state health information exchange. We hope that the states will provide valuable leadership that is closer to the local healthcare market than the federal government is. We know states vary enormously in their capabilities, their track record in this area, their preparation to provide leadership, but we were convinced that the states have an important role to play. That they can be leaders in many areas, and where they're not leaders yet, they need to be part of the process of getting to health information exchange.

The Congress also informed us that the training of a workforce to support health information exchange, to support adoption was important, and so we've invested in that as well, $118 million in training up to 45,000 health information work professionals, some with certification degrees, some with BA training, some with Masters and above, and we've created sort of a framework of four separate complementary programs that will support that training function.

Then we knew and the legislation suggested that innovation was an important part of this, so we invested in research through a strategic health IT advanced research program, which is going to fund four centers to advance the capabilities of health information technology in targeted areas. With the discretionary funds available to us, we knew we needed to build an infrastructure for exchange, so we have invested $60+ million in accelerating the process of the Nationwide Health Information Network. And, as we get more advice about the various mechanisms of exchange that will make sense for meaningful use, we are thinking about whether there are complementary, consistent, alternatives to the full NHIN as ways of undertaking exchange.

Our health information technology policy committee recommended to us that we explore that at our last meeting. They're going to come back with more concrete recommendations at our next meeting next month. So we are developing, as we speak, a set of possible programs to accelerate the use of Nationwide Health Information Exchange mechanisms that might be simpler, easier, less robust perhaps, but also easier for small providers to access in the short-term than the Nationwide Health Information Network.

We're working hard on privacy and security as well. We have a taskforce of the Health Information Technology Policy Committee that's looking at additional protections that may be needed, and the Office of Civil Rights is developing regulations to implement some of the provisions of HITECH that are relevant to privacy and security. As you can see, with our colleague agencies, have spread our wings pretty far.

Whether we've taken off or jumped off a cliff, I'm not sure. But we know we have big responsibilities and that we don't have any time to wait and see how one program works before we start another program. All these are going out in the field simultaneously.

It's a big order, but we've had a lot of support and help, and we're grateful for that. And we think that in so many ways we're pushing on an open door because we are part of a historic movement that will get where we want to get sooner, we hope, than later. But we'll get there eventually, so we just hope not to knock it off path, as we try to move it along. Thanks for the opportunity to summarize all that.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks, David. I think the list not only offers the opportunity for learning, but also very clearly articulates the direction of interest and hope that our committee members will think about those signals, as we contemplate the next set of activities.

We outlined a few of the things that we've talked about this afternoon, and the way of teeing up some of the discussion, each of the committee chairs, I think, has put together one slide. Before we get to that, John, I know you have some thoughts on direction as well. Anything you want to offer or dive right in?

John Halamka – Harvard Medical School – Chief Information Officer
Well, certainly you, David, have just raised a very important point to me. I keep writing, as I've said it in my blog, about data transmission and the use of the NHIN and simpler ways than the NHIN. And so if there are further details that you could provide to us on what your thinking is there, as we, both privacy and security and clinical operations and quality, we're going to comment on the IFR. In fact, that may color some of our comments to understand what you guys are working on behind the scenes.

I think one of the more important things you said this morning was achieving the balance between market and regulation, and if you have reference of implementations, oh, and there may be some market developments and the regulations all together, then hey. Maybe there are aspects of the way the regulations are written today that are exactly perfect and that our comments don't need to be quite as extensive as we might have otherwise made. So I certainly look forward to learning more about that. But I think what you'll hear from each of our working committees is that they are ready to charge ahead with the challenges the IFR has created in terms of standards harmonization and making sure that it all cohesively works together.

Jonathan Perlin – Hospital Corporation of America – CMO & President
With that, let's turn to Jamie Ferguson. I understand – I believe you should have a slide that's teed up.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes. We have a single slide for clinical operations next steps. And so we've divided this up between the longer-term and the shorter-term priorities, although six months here would be longer-term. And what we're seeing here is that over about the next six months, we really plan to focus on the things that were in the interim final rule. There's plenty of instruction there for the work that's needed and what our next steps are.

We're really taking the perspective that that work supports the policy objectives and the intent of meaningful use with specific items for the meaningful use objectives and measures that were outline, both in the NPRM and the interim final rule. But within the next six weeks, in the very short-term, we'll really support the implementers to help them gain the ability to comply with the IFR by essentially trying to polish and refine the existing IFR with our comments, and so we'll do that with the things that are relevant to the content exchange and vocabulary areas that are in scope for us.

I also want to touch on the vocabulary taskforce where we're really focused there. We have a meeting there tomorrow. We're focused on both the convenience subsets, things like the most frequently ordered lab tests, the most frequently used problems, and so forth, as well as the value sets that constrain the particular codes that are required, for example, for quality reporting. And so we're going to discuss those requirements and priorities and sequencing of those things tomorrow. We're also, in the vocabulary taskforce, planning to discuss and ultimately make recommendations on some of the processes for the development and maintenance, the management and communications of both the value sets, as well as the convenient subsets of the controlled vocabularies.

Someone here today commented to me that the focus really has shifted from the policy goals of meaningful use now to technical compliance with the IFR. And so I think this actually fits with our short term focus, so what we're saying is that in the short-term, you know, we do plan to try to help the implementers with comments that would be helpful in that refining mode on the IRF, but that in six months, in more of the six months view, taking a look at the work that's outlined for the workgroup. We also want to look at the broader meaningful use policy goals and objectives, and take the IFR as a given. Then see how could we support those goals with our next round of work.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let's open for some discussion on this trajectory. I know that some specific issues actually implied in terms of the content exchange and vocabulary. Has the group been able to contemplate, even this early in the process, a way to segue from best in class recommendations in a particular domain to a way to have harmonization trajectory to move from raw material to the useable code and the implementation? But to provide clarity of – you've got markers in the sand for 2011 that are very clear. There's clarity in 2013, and there's more ambiguity further out.

And there are two ways of resolving that. One is with, again, replicating specific domain solutions in each cell further. Another alternative that provides clarity without being as specific in the absolute, but a great degree of clarity going forward is to create a blueprint for forward harmonization. How is the group, or is it premature to contemplate that? How are you going to segue to that?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Since the rules were published, we haven't had that discussion yet, but that's exactly some of what we have to discuss.

John Halamka – Harvard Medical School – Chief Information Officer
Just to add a bit more detail in terms of some of the things you're suggesting is that in the work that HITSP has done and, to some extent, the work that we've done, we've looked at what are those CDA types of constructs that might be reusable for different purposes. Now if you look at the way the IFR is laid out, you have HL-7 2.3.1, 2.5.1 for very specific purposes. One asks, well, if HL-7 has this CDA template idea, might you take a CDA construct and use a templetized set of data in CDA for multiple purposes, both primary and secondary use? So it's an interesting question.

How much is narrow for a specific domain, and maybe you argue e-prescribing is great as it is. Don't touch it. But how much might there be a path over years to think about, well, here's a transaction that I could use for lab. Oh, and I could also use it for biosurveillance. I could also use it for public health reporting, and it's all part of a larger construct. It's this whole question of how much change, how mature are the standards, how implemented are they, things we've all grappled with before.

Jonathan Perlin – Hospital Corporation of America – CMO & President

Thanks, John. Jodi Daniel?

Jodi Daniel – ONC – Director Office of Policy & Research
I just have a question about whether or not your workgroup is also planning to look at the related certification criteria, as well as the standards, in the particular areas that you're focused on.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, absolutely.

Jodi Daniel – ONC – Director Office of Policy & Research
Great. Thanks.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Any other thoughts in this area?

John Halamka – Harvard Medical School – Chief Information Officer
There was one question that was asked of me, which was, administrative simplification. Now, if you think about it, we have clinical operations, which is focused about clinical data exchange, security and privacy, quality, implementation, but we actually don't have a workgroup specifically on X12, 4010, 5010, and payer/provider interactions. And so, given the VIFR actually does have administrative simplification content, what group works on any comments? And so, Jamie, what I might propose is, in a sense, you've become kind of a transaction workgroup, and there may be – Ann, I'm sure you probably have comment. You don't sit on Jamie's group – that those who have payer or administrative simplification domain expertise would contribute comments through Jamie's group that could be vetted there?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Sure. I think that would also fit with the previous work that we did in the clinical operations workgroup where we considered all the different content exchange packages, if you will, including making recommendations on the administrative simplification transaction, so I think that's a good fit.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Judy Murphy, you were going to comment.

Judy Murphy – Aurora Healthcare – Vice President of Applications
Sure. One of the things I was thinking might be really helpful when we start talking about implementation guidance that maybe your group could take the lead on is simplifying the information. Doug Fridsma's third slide was a crosswalk table, and it showed the criteria measurement, and then the standard that applied. That to me is going where we need to go in terms of helping the public understand what many of us hopefully at least understand at some level.

Doing those kinds of things and publishing those officially as implementation guidance I think might be really helpful. Then maybe even in the column where we have the standards, give some key references or some key examples, Web sites, organizations that have done this thing well. I'm not exactly sure. I get a little iffy around what we could provide as examples there, but I think that crosswalk thing. And I don't know if Doug entered the room again, but is that crosswalk completed for the whole thing? No. Yes, so just a thought in terms of the standards. It might be really helpful, I think, to drive that home for folks.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

So one of the things I thought I heard you say was a recommendation that we also then essentially extend that crosswalk to show some of the EGs, like implementation guidance, reference implementations, and so forth.

Judy Murphy – Aurora Healthcare – Vice President of Applications
Yes. That's correct.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Other? Wes? I want you to keep going with that optimism vein. They're really encouraged….

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Another optimistic thing was a comment that David made this morning, and I certainly hesitate to put words in his mouth, even after he's spoken them, but effectively we have faced a dilemma in our industry, not unlike the way other healthcare related things have been defined. We have a lot of powerful groups, sometimes vendors, sometimes others, where not doing anything is second best. And it takes some sense of not doing anything is economically painful to get them to give up on having priority in their points of view and things like that. After we get through the immediate business of responding to the regulations, I'd like it if we could find a way to look at the way to convene a forum for those who have decided they have to agree, if you will, and how to follow the guidance that Carol has mentioned several times.

One of the comments this morning was, well, the IFR isn't USB. I'd like us to remember that USB wasn't USB for about five years. And so somehow I just realized by the time I got to the end of the sentence that there's probably already a group set up for that, and I was not thinking about it. But clearly all of us who feel the same dissatisfaction we felt every year for the last 20 years, okay, the spec is out. Oh, it's not plug and play. I mean, we have a different view of the process now, and I'd like to see us be instrumental in carrying that forward.

David Blumenthal – Department of HHS – National Coordinator for Health IT
If you actually read the HITECH legislation, it speaks of the standards and policy committees as being forums in which these issues are discussed and advice is formulated. Now I don't know if you feel or if … actually are working. Let me back up and say there's no question that you provide that forum. That doesn't mean that you speak for the entire world or the entire nation, but you bring incredibly valuable and diverse perspectives to bear. So I think, if you continue working to guide us to resolve some of these issues, that will be an enormously positive development. If you all come to concensus on something, it will be influential with us. And that's not to say it'll be easy to get to, but it will be important.

Jonathan Perlin – Hospital Corporation of America – CMO & President
…prerogative to react, I think what's different are two things. I keep reflecting the tension between the concerns about under- and over-specification and, frankly, under-and over-aspiration. There is a sweet spot, and I think the dialog has really been helping to move as responsibly and responsibility to that. What strikes me as different is that you can't move in the absence of that. You made that comment, and it really, I think, resonated with the group this morning.

The other thing that I think is different is that the economy context has changed, and the incentives are a powerful, motivating force to act on that. And in the context of a coherent set of specifications, really, I'm optimistic that will that lead to different behaviors than in prior times. I share that with you. And I also heard the second piece, which really gets to the discussion about implementation guidance, that there is a distance from specifying it to making it operational. Anne Castro?

Anne Castro – BlueCross BlueShield South Carolina – Chief Design Architect
What I heard was we're the group, the answer to Wes' question, and that we need to start bringing up what we would recommend and represent our complicated mixed interests in that so that we shouldn't avoid talking about what we would do in 2013 and what we would do in 2015, and that we shouldn't water it down completely. Again, it's still a balance, but we'd say, here's where we really think we should go instead of not discussing the topics. And yet, since it's public workgroup meetings now, that should be open to people to begin having comment on, so if we go left or right or somewhere that we shouldn't, we should have immediate feedback. So I would look for our workgroups to step up to talking to those future requirements that people want to know what we're thinking, so that that's really the path, unless somebody comes along through the public openness to stear us in a different way. I'm thinking, Wes, I'm with you, but I think it's us. It's not another group.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Having said that, and I'm delighted that you feel that you want – what's the right word? I'm delighted you feel like you have something to do, that you have a contribution to make, and we are looking forward to that contribution. We need that contribution. We have to – there may be other venues that you want to – in addition to the working group, there may be other settings that you want to meet in. There may be other ways in which you want to get input.

As we get further down the line from 2011, there may be areas where we can be more specific. You can be more specific than you've been under the pressures we've had to get an IFR out by December 31st. Also, as the public and the stakeholders become more accustom to our work and find ways to get their views heard, and also as they may get more comfortable with the idea that the federal government will specify things more directly. But we're also going to be dealing with this balance between over- and under-specification. And we're always going to be doing midcourse corrections.

Jonathan Perlin – Hospital Corporation of America – CMO & President
As David said earlier, in addition to our community work, you retain your first amendment rights. Indeed, that's part of the dialog that we're encouraging the public, but I think we have to lead by example as well and provide input into the public process, the comment period specifically. Just to be sure the point of this group and our activities are really to come to concensus from a breadth of backgrounds and perspectives on really helping to provide recommendations to the Office of the National Coordinator that strike that balance in the best possible way that remain aspirational, but not unreasonable, and that really is – I think that's worked thus far, and I think that's likely a good sweet spot. As someone put it at lunch, the Goldie Locks spot for future.

Now the point of work though is not just the transactions, so let's segue that. The point is that the transactions – I'm sorry. We have another comment on this area.

Unidentified Man
Just quickly, I want to follow up and push on Anne's comment just a little bit. So you could read what Anne said as saying that this group might make recommendations that would never become regulation or anything else, but would represent one diverse group of people who represent this field, having thought about this carefully, that would make recommendations that might guide practice. There might be sort of suggestions about best practice that would let us work at a separate level than everything being in regulation, but would give people more information, more guidance than they will get otherwise. Is that on the cards?

Jonathan Perlin – Hospital Corporation of America – CMO & President

I'm going to ask, perhaps, David, to jump in, but this goes back to our very first meeting is that, in fact, in the statute, in the legislation, it talks about implementation guidance. Toward that end, those are the things that are more protium that in fact you wouldn't want to lock down and probably couldn't be locked down in regulation, so that is a parallel activity in deed straight out of the legislation, an activity that is attributed to this and the parallel policy committee process. Anything that, David, you want to elaborate? No?

John Halamka – Harvard Medical School – Chief Information Officer
Just a comment I would make, and that's exactly what I've been talking about in this balance between regulation and market is that if we discover, oh, you're putting a lot of money into FHA CONNECT, and that's actually seemly pretty good way to connect to federal government agencies. Oh, but then there's a consortium of private companies that have done something kind of cool and interesting, and we all look at it and say, gee, it seems kind of reasonable. You know, it does this over TLS, and it's restful, and it seems to adhere to our general principles. And we would highlight as resource.

Then the community is screaming for ways to do this. And so when I talk to vendors, and they say, I now need to communicate via the patient's communication mode of preference, a clinical summary. How do I do that? Is that e-mail, Morse code, smoke signals, Facebook? I'm not really sure. And so it's not regulation. I mean, there might be some specificity that it could only be fax, e-mail, or a secure, electronic PHR transaction. Maybe that's a polish item to add to the IFR.

But if we, together, found four or five interesting, what we we'll call, healthcare hub products, and this was a bit of implementation guidance that seemed to adhere to the spirit of the IFR, but it's no regulation, and they seem to generally include our basic principles, the community would love it. The one thing you don't want is a thousand wildflowers blooming. You hope there's innovation, but the ultimate goal, it may take years, is that states would be able to talk to states.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Cris Ross next.

Cris Ross – MinuteClinic – CIO
…an issue of what should practice be, and then also how to do it that John just talked about and others. And it seems to me as though the implementation workgroup hasn't had a chance to sort of get together on this issue. But I think we've got to figure out how clinical operations and implementation, along with the other groups, sort of combine their work or coordinate their work because there may be more than one way to accomplish a particular outcome based on standards that are already articulated by operations group and so on. So I look forward to us figuring out what we want to do on our turf, but then also communicating about how we can not be plowing the same ground.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Great comments. Carol Diamond, next.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Yes. In the spirit of that comment, and also with what I think Wes was trying to ask about, you know, I think when we did the implementation hearing, we developed those top ten takeaways, and they were really, I think, illustrative in going back and looking at some of the existing standards of where you might want to draw the line or where this meets some of these issues, the standards might be appropriate, this one might not be.

My sense is the way to operationalize what Wes was asking, which is how do we not make the mistakes of 20 years, or repeat the mistakes of 20 years, is to try to operationalize those criteria a little bit as a committee. I know I joined the committee later than most of you, and one of the things that I was sort of groping for was the gestalt that the set of sort of criteria or let's call it standards policy that needed to guide our deliberations and guide our thinking because there's an endless array of standards in every one of the areas that we've been looking at, whether it's transaction or security or quality, and there will be more than there are today. We can guarantee that a year from now.

It seems to me that in addition to just sort of looking at things on whether or not they're interesting or they generally follow some of the earlier recommendations, it would also be interesting to see if we could operationalize from a process standpoint a set of criteria that we start with in those discussions. Certainly on a go forward basis with new standards or new recommendations that we might have, it just feels like we're lacking that structure in terms of a process.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Very good recommendations there, and what I'm hearing is a very purposeful linkage with what we've been calling the … specification, and I think there's a level of maturation that also has occurred through the process, so that's good guidance. Toward that end, let's go back to the segue to the next set of future work, which is that the transactions … just for the sake of being coherent transactions, but to support a set of processes for care delivery and communication of information, improvement of outcomes. Fortunately, I do think there has been a very purposeful trajectory. In fact, even this afternoon's discussion was sequenced in thinking about those transactional elements as a prerequisite for those derivative purposes, and not to diminish those purposes. Let me ask Janet Corrigan to lead us through some comments on the next sets of activities in the clinical quality arena.

Janet Corrigan – National Quality Forum – President & CEO
Thank you, Jon. Yes, the quality workgroup, we too have some short-term priorities, as well as longer-term priorities, needless to say. In the short-term, we'll be having a conference call next week on January 27th and, at that time, we'll have a chance to really go through the meaningful use provisions that are in the current rules. And I think what we'll want to be doing is to take a very close look at the measures that are reflected there. As I indicated earlier, there's a whole core set that are the ones that really were recommended that came forward from this group, but then there are many additional ones. I think part of our challenge is to look at those additional measures that are included, see how well they line up with the quality framework that came forward from the policy committee.

We're also going to want to take a close look at whether or not there are harmonization issues in terms of how those are specified, given that we've now got a lot more of the individual practitioner level than we do at the hospital level to see whether those are harmonized properly. Last, but not least, whether there's any implications for all of the retooling work that's just getting underway or the continued evolution of the quality data set, the QDS that is basically based on. Next week, we'll have a chance to discuss what's in the current rule and provide some immediate feedback.

Our long-term priorities though, here is where we really want to start to think a good deal more about 2013 and 2015. We are going to be awaiting, to some extent, I think, some additional guidance coming forward from the policy committee, which does have a strategy group in place that's thinking quite a little bit about the future and how this should evolve. But in the near term, we can certainly take a look at what we already have from the policy committee for 2013 and 2015 and start to think about what measures, performance measures we should line up for those two years.

Now this is going to be heavier lifting because we have now taken advantage of, I think, virtually all of the low hanging fruit that there is in terms of performance measures, so as far as ones going forward, as we begin to raise the bar on those measures, I think probably some of the measures that we're going to want to tap will be ones that are yet to be developed that correspond directly to what the policy committee is asking for because there were various measure gaps and others that may be in the pipeline. And there is about a two-year development period for measures, so now is the time to begin to think about that if we want to bring on new measures for 2013 and especially because it's going to be a pretty tight timeframe.

In addition to that, I think we'll probably also want to give some thought to two other areas, which is how the performance measures relate to the CDS meaningful use requirements. And as we look at this, and moving towards how we get the greatest improvement in outcomes over the next five years or so as a result of this work, it may make a whole lot of sense to think about how the CDS requirements line up with the measure sets and how the measure sets move to process and eventually to outcome measures. In addition to that, there's a lot of developmental work going on around, as I said, sets of measures that really do look at a complete patient episode, and we may well want to tap into some of that as we look to 2015 kinds of requirements. That's pretty much what we'll be sinking our teeth into.

Jonathan Perlin – Hospital Corporation of America – CMO & President
That sounds like a very ambitious agenda and operating at a variety of levels from the first principles of what is clinically and socially important to the elements of data to the internal coordination with other aspects of meaningful use, such as the clinical decision support. The reason I draw that out is that really gets to the point of the last discussion is that it's impossible to think of this simply in data terms. One really needs to consider these activities from the perspective of the implementation. I think there's, in a sense, ditto to the prior discussion about the ways in which not just the work of the standards committee through its charge in implementation specification, but through the other venues that David alluded to really serve as a set of references for implementation and operational success. I see a card going up at the end, and that's John Derr.

John Derr – Golden Living LLC – Chief Technology Strategic Officer
Yes, I wanted to build a little bit on what Wes and Jim, and the rest of you talked about. As we go forward to 2013, and Ed, I think we should be taking into account what's called under meaningful use "other providers", and that we should think about the nursing homes and the homecare agencies and the other people, how they fit into this whole longitudinal record thing because most of you know the frustrations I have sitting here that we're not in meaningful use. Janet and I have worked on a number of quality measures, but the system won't work unless we can, when they discharge from either an office to homecare or nursing homes, we have these quality measures across, and that the longitudinal record goes.

We're still working on those as a shadow group as, Jon, as we said, a number of months ago. But I think, in the spirit of things, to make this whole system work, we have to have these other providers and talk about them and how they fit into the whole integrated, personal, centric record. I applaud that we would, maybe after the comment period, that we would have some time or think about, as a group, how this fits into the "other providers" that are in the legislation.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks, John. I think there is this foothold in the edition that Karen Trudel spoke of today, provide summary care record for each transition of care and referral, and that would seem like….

John Derr – Golden Living LLC – Chief Technology Strategic Officer

Yes. There are a number of things in there that people over 50 years old. I mean, if you look at the 555 pages, because I got it down to 21 pages that applies to our sector, and there's a lot of things that we have to do in transitioning patients and being able to do it, rehospitalization and all that. And if we're not part of it, then you'll send us something, and we won't be able to take it. Or we'll have a patient for rehospitalization, and we won't send you the information. I know we aren't in legislation, so I keep quiet most of the time, but after we get to a certain point, I think we should be considering the whole spectrum of care in how we do this. Otherwise, I don't personally think it will work.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks, John. Great points. Stan Huff, I think you were next.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
I wanted to follow up on some of the comments that Janet said about selecting the next measures, and in fact reflecting on the measures that have already been selected. From a provider point of view, our ability to do the measures that are recommended by the committee come from a common pool of things that we have to sort of do everything to do with IS in our organization. And in some ways, I feel my degrees of freedom within the institution decreasing as we create more and more measures that are coming from a national source.

I would argue that these are good measures, and there's every expectation that they will have the impact that's implied, but I think actually we have probably a higher obligation or a need to think about how individual institution goals and quality things are impacted by this because what could actually happen is that the national things are good. But then we're not doing better things that we actually could have done in the institution, and so it's being good isn't sufficient actually for us to recommend adoption nationally. And this is ill form, but it seems like we need to think about that.

I know, within Intermountain Healthcare, we have basically we're charging clinicians in many cases to say what is it within your area of domain should we be doing to improve quality and reduce variability and improve costs. And so certainly we want national measures, and we want that direction. I just would like to have some way that we could either evaluate or think about, as we do that, are we starting to now focus in a way that won't provide the greatest benefit because even though it's good, it's not the best thing that we could do in a given institution.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Janet Corrigan?

Janet Corrigan – National Quality Forum – President & CEO
It's a huge issue that you raise, you know, what is the balance between the measurement that sort of comes down from on high or externally required versus that which is the priorities for any individual institution. I think it also relates to another issue, which is, are the measures that are included in meaningful use for payment purposes like CMS or others? Have we really thought through the process for making sure that we're tackling the most important strategic areas that are really going to lead to the greatest improvement in terms of outcomes? They're both very clearly related. I think that's something that has to be grappled with, as you go forward, as we all go forward, which is how much is enough. How far do you want to go on measurement? At what point do you take some off the table?

Now if you look at that earlier chart that was put up that showed the trajectory moving initially from collecting the basic data to process indicators to outcomes, I mean, at some point in the future you'd like to think, many of us would, that we'd be focusing an awful lot on outcomes and leaving to the individual institutions to define the care processes that get to the best outcomes. If you're achieving good

outcomes, then we should be pretty darn comfortable with care processes. We're not at that point yet. And, for the foreseeable future, we're probably going to be looking at both process measures and outcome measures, hopefully paired in a rational way, tackling the most strategically important areas. But I think that's a key issue.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Fortunately for this committee, we don't have to reinvent, and you referenced earlier or was referenced earlier that … national priorities partnership to really take the lead. Jim Walker?

Jim Walker – Geisinger Health Systems – Chief Health Information Officer
Just real quickly, I want to reinforce the suggestion that as soon and as much as possible, we really focus on the whole healthcare team with our quality measures, with the communication standards. I mean, it cuts across the whole spectrum. We've been going out to our region trying to organize beacon community, and the most frequent thing that hospitals, clinics, and case managers say is I don't have any visibility into the long-term care facility, and it's extremely hard to manage the care of patients that go into and stay in those facilities.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Great points. Terrific discussion on this topic, and then, of course, Dixie Baker and team and Steve Findlay a terrific job of steering us to date in terms of privacy and security as both a prerequisite for trust and … facilitators, so I very much look forward to your comments, Dixie.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Well, the workgroup's priority for the next six weeks is pretty much established. The next six weeks, we've established a timeline for getting our recommendations to the full committee by the February 24th meeting, the next meeting. We've distributed to our workgroup members a set of questions that are really based. They're based upon the general approach. Some questions have to do with the general approach that the IFR takes, and other questions are directly from the solicitations for comments that are embedded in the IFR.

We've asked our workgroup members to respond to that set of seven questions. Walter Suarez is helping me put together the responses that we get from our members, and then we have a number of meetings next week. We're meeting to go over what we heard today and to tweak our questions if we need to, and then the workgroup, their comments are due to us by February 12th, and we will be presenting our results at the next meeting. We have asked our workgroup members. We haven't discouraged them from commenting about vocabulary and content, but we've asked them to direct their questions that they have regarding those two topics to the respective workgroup chairs, as well as implementation and adoptability.

So beyond the IFR review, as you know, there's a new – you know, as opposed to what Jamie was saying, the policy is behind us and the standards are ahead. Actually, the policy workgroup has just formed a privacy and security workgroup that's had the policy committee. We've just had a couple of meetings, and so we're really looking for what comes out of the privacy and security workgroup of the policy committee to guide what we do in the future because, to date, the standards that we've recommended have been based on HIPAA, as well as some assumptions about what the policy is likely to be for health information exchanges and for healthcare, eligible professionals, and eligible hospitals in the age of meaningful use. So we will align our standards with what we see coming out of the policy committee's privacy and security workgroup. Then we will plan for incremental updates to the standards and implementation specs and certification criteria.

We do expect, just based on my involvement in the policy committee's privacy and security workgroup. I expect that what we'll see in the future will have much more to do with patient engagement and with personal health records than what we've done so far because that seems to be a major thrust of that committee. And I know some of my workgroup members would be happy to address those topics.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Terrific. Any comments on the set of work? Okay. Thank you, Dixie and Steve, and to all members of each of the workgroups for all of the effort. Move to general comments, anything that anyone feels that is left off in clarity on the forward agenda? I invite Doug Fridsma and John Glaser, if you feel that we need some refinement in terms of target. Feel free to please tee those up. David Kates?

David Kates – Prematics, Inc. – Vice President Product Management
Sure. Thanks, Jon. One question or comment related to some of the earlier points that Anne made and others made in terms of the intent of the IFR and the NPRM, I know we're anticipating regulations around the certification process, but there are lots of questions and potentially comments that this group might make, as it relates to the modular certification process, and as we contemplate modular EHRs. I didn't know if the implementation workgroup, which I'm working with Aneesh on, so maybe I'm volunteering myself, but that might be the appropriate forum for which to provide some of that feedback, to speak to questions that arise from the IFR and NPRM.

And, specifically, and related to that, in reading through the IFR, to some extent, I know we've all said that the intent is not to presuppose an architecture of a technology implementation, but some of the language and semantics in the IFR imply architecture. For example, the clinical decision support requirements imply that there's a clinical decision support system within the EHR, which may or may not be the case. There may be clinical decision support intelligence in the cloud that's served up through the EHR, so really the question, where do those types of feedback best be delivered.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I think this is going to be one of the key areas, and it's obviously going to have to be a multifactorial process to get these responses in terms of decision support. Actually, that provides a good segue. We've talked about each of the sorts of building blocks, but the rubber hits the road through implementation. Aneesh?

Aneesh Chopra – White House – CTO
Thank you, Jonathan. David, great question. We have a conference call Tuesday, for those of you that didn't get the message out or have not confirmed. I think it's at 10:00 a.m., so precisely what you've asked is in scope to the conversation that we want to have as a group, which is how much of our energy should be focused on learning from the ground. What are the rubber meeting the road questions that need to be addressed? How do we go about prioritizing the two or three that need to get our immediate attention impacting 2011? And obviously, as we transition towards the 2013 work, where are the areas that we need clarification and providing that feedback up, so that's exactly the reason why we're going to have the call on Tuesday to hear these practical questions.

Jonathan Perlin – Hospital Corporation of America – CMO & President
I think David McCallie had his card up.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Yes. It's David. Just a general comment, picking back up on the theme about the tradeoff between specificity and flexibility or innovation and picking up on Jon's comment about the USB. I was thinking

about how metaphors are very useful, but they can also be very dangerous if you get the metaphor match to reality wrong.

So I would suggest that the healthcare system is more like the question of the whole computer rather than the USB port because, as you remember, USB was competing with RS232, FireWire, FireWire 800, and a variety of other interface terminologies, each one of which had to refine its own standard, but then they all had to compete with each other to determine what the right niche and what the right markets were for those technologies. I would submit that healthcare is more like the computer system, so there may be a role for USB and FireWire depending upon what you're doing. And it won't stop. There's already USB3, right, so I think we have to be cognizant of that. It won't stop in healthcare either, so we should keep it open.

Unidentified Man
David had about three hours to think of that….

David McCallie – Cerner Corporation – Vice President of Medical Informatics
That's why I haven't said anything all meeting. I've got to get this right.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks, David. I think the committee interactions to this meeting and every meeting illustrate that we have actually a remarkable … together. I will tell you, having over the course of the last decade served on many committees in many groups, sometimes there are political landmines and … challenging personalities, and all those sorts of things that you get. This group, in e-mail, and I get dozens of e-mail every day from all of you, is not afraid to tackle the tough issues. There's no third rail. We just put it all out in the open, and we say things publicly, and we're not shy. And so I am convinced that all of these issues that we've talked about today about the balance between specificity and innovation, between market and regulation, that this is a group that is going to be able to address that stuff. And we will suggest things, and then I we discover that they aren't getting implemented, then we'll revise them. I don't think any of us comes to the table with a particular endpoint in mind, other than the improvement of the healthcare of our patients and interconnectivity throughout the system, and then probably, in your words, improving quality and efficiency.

My hat is off to you because I feel like, over the last, wow, it's almost been a year, well, no, not quite a year of working together. It feels like a year. It feels like we've been able to move the ball forward. Fine, there are certain unanswered questions that the IFR outlines for all of us, but I have absolutely no fear we'll be able to, in the six-week plans and the six-month plans, tee those off and get those back to you, and then as you said, it'll be right. I have no doubt…. Anne Castro?

Anne Castro – BlueCross BlueShield South Carolina – Chief Design Architect
Thanks. I have a question about the SHARP projects and how that would integrate with us, when we will coordinate with their work because some of the topics really from just the written words looks like it crosses over on things that we'll be working on in the same timeframe. And just looking for when we'll hear more about that coordination.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Thanks for that question. That is a research and development group, and we're actually taking applications. Actually, I think applications may be due on Monday. I think if you want to learn more, we could have Chuck Friedman, our chief science officer, who is running that program, come by and talk with you, and we could chat with him about areas of overlap.

This is our effort. It's not as big an effort as we might like, but it's at least a stake in the ground in a commitment to moving the science of informatics and the technology forward in a way that is not focused on the next – it's partly focused on the next three years, but it's also equally focused on the period beyond that, so it's a little more aspirational in terms of its long-term effects. It's not – we're not tasking these centers with helping us get to meaningful use by 2011. I think it's much more about fundamental breakthroughs with some practical spin-offs. The balance between that, we're going to have to see what the applications are like. But I think it would be fine to have Chuck come in and tell you a little bit more about it.

The program, the FOA came out mid December. It was done, like everything we're doing, on a very fast track, and it will be funded on a very fast track. It's going to be funded, though, as cooperative agreements, as all our work is, which enables us to continue to negotiate with the grantees about the terms of the agreements, so we do have a chance to influence what they're doing going forward, and we can take your recommendations into account.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Cris Ross?

Cris Ross – MinuteClinic – CIO
I think one of the things that I was going to try and suggest to the implementation workgroup on Tuesday is to the extent we might identify some particularly difficult implementation problems where we have major conflicts between small-scale and large-scale practice, or anything like that where we know we've got a real conflict that if we might surface some of those issues as potential investigation areas for SHARP grants, that we could get some real life experience or some laboratory experience on how to solve some of these gnarly problems that we know are going to be in the way. So it would be nice to hear from the program directors around that program, so we could really know more about it.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Aneesh?

Aneesh Chopra – White House – CTO
I just wanted to make a general statement about the use of these R&D centers in areas like homeland security and others where we've really tried to align need with research, scope, and area. A great deal of the work that I do is coordinate the R&D activities across the federal government, and a major focus is finding a way to marry relatives with the ideas. So I think that combination is what we hope these world-class applications coming in will be. If you haven't submitted your application, and you're listening to this or being part of this, get it in right away.

We hope these are going to be – I'm hopeful that these are going to be centers of excellence that will be a model for the rest of the federal government on how to do both cutting edge research, but also to have relevance on key priority areas for the country, and there will most certainly be, at least in the requirements document that was published about the no … or whatever they call it, it was really explicit about this need to have an understanding of the need in the market and so forth, so this will be an exciting tool to work with.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks for that. Anything else, Aneesh? Any closing comments on implementation go forward?

Aneesh Chopra – White House – CTO

You know, listening to the conversation here and inventorying a number of the things that have come up during the break, we're going to have a lively debate on Tuesday to sort of really get at the top two or three areas we're going to want to get real, meaningful activity in. But this group won't be shy. Jon, we're going to follow the lead, and be supportive of all the activities that you've laid out for us to accomplish in a short period of time. But I have great confidence that this is going to actually be the deliverable collateral, if you will, to help get people to adopt these tools and these capabilities to achieve meaningful use sooner and faster.

Jonathan Perlin – Hospital Corporation of America – CMO & President
It's where it becomes real, and so we appreciate your leadership, and all the members of the implementation workgroup. Let me come back to Doug Fridsma and John Glaser, Jodi Daniel, anything that you're seeing as potential gaps in terms of drawing on the actual language of HITECH and the process, anywhere that you want to draw our attention to?

Jodi Daniel – ONC – Director Office of Policy & Research
Nothing that I could point to at this point. Like I said, the one thing that I had raised was just making sure that folks are exposed on the standards and certification criteria, but I'm not aware of anything else that needs to be addressed, but I'd leave it to Doug.

Jonathan Perlin – Hospital Corporation of America – CMO & President
What would be helpful for me is, as kind of a cochair project manager role, is if you guys had a scorecard of the assignments that were made to this committee in the IFR that we could track, you know. By 2013, you will figure out the right patient summary format that could be used for a multitude of purposes. Great. Where are we on that?

John Glaser
I didn't want him to be alone in front of you all. You might be collegial, but you're a tough group.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Let's go to Doug Fridsma and John Glaser.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
I think that that's right. I think it would be helpful for us to sort of take a look at, from the ONC's perspective, kind of what progress we've made, take a look at sort of the initial charges that we had, and the progress that we've made. And then I think, at that point, see what we anticipate or some of the things that we need your input for, as we move forward with this. I think we can help provide some of the questions that we have that we hope that you can provide some input.

I think the other thing is that there may be an opportunity for you to get input from our office about some of the things that we're doing to help operationalize the suggestions and the comments that have come from the committee as well. We'd be happy to provide you those sorts of updates.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thanks. John?

John Glaser – Partners HealthCare System – VP & CIO
Yes. I think, first of all, the kind comments you all made about the quality of the IFR is a terrific reflection of your all's work, so I just want to make sure that the praise is broadly shared, and you all ought to be proud of the way that it looks because it bears your imprint in many, many ways.

I think there are three major threads of activity for you all in the months ahead. One is very immediate, which has been mentioned by a lot of the workgroup chairs, which is comments on the IFR. And, reflective of David's comments, it's hard to add, but it's easy to subtract is, you know, where there are differences from which you all proposed and what's in the IFR, what are they, which ones would you like to serve up for 2013, if not possible for 2011, so that's a fairly near term set of activities.

The second major thread, which has got multiple pieces to it and was brought up multiple times, the industry is trying to figure out how do I make this happen. And some of it is providing clarity about options that no, it's not smoke signals, but Morse code would work, those kinds of things. But whether it's the crosswalk, as Doug had given a snippet of, or other types of guidance, and whether it's continue to work, for example, Janet, and making these things EHR ready. Whatever it is, it's got to happen in the very near term, so the industry can move as effortlessly and as flawlessly as it possibly can. I think that is the second thread.

I think the third thread is a little bit more of a mixture of stuff, and it's more intermediate term. Some time in the next multiple months, we'll have to come back for 2013 meaningful use. We haven't exactly figured out the timetable for that, but it's probably on the deck somewhere there. Doug and his colleagues have done a lot of work, still a lot of work to do internally about how to set up a process for ongoing harmonization of standards, standards development, implementation specification. And, at some point, that ought to be presented to you all and say here's what we are thinking along those lines.

I think I would also encourage you to look far a field, and that is perhaps to take on topics like semantic interoperability. Where are we, and how quickly is that likely to happen, and what should we be doing in those particular realms? So some very near term work to be done on the IFR, near term work to be done on implementation, and I appreciate the immediacy of all that, but also to set your sites on some stuff, which is not only this calendar year, but perhaps beyond that on a wide range of topics for which your guidance would be terrifically appreciated.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Many thanks to both of you for that additional guidance. That's very helpful, and I think it relates both on a theme. Let's go to John Halamka. Any closing comments?

John Halamka – Harvard Medical School – Chief Information Officer
I think today has exceeded my expectations in that I have learned an immense amount about all of the pressures that you guys faced in crafting this, and how now a path going forward short-term and long-term will actually get us to move the industry to where they need to move. And so, I had read these regulations in a vacuum, in a sense. You know, I took them for, oh, what has the work of this committee been, and now what's rendered into a document without the knowledge of the whole ecosystem that you've had to work with? And so I actually feel even more positive….

John Glaser – Partners HealthCare System – VP & CIO
Shall I keep talking?

John Halamka – Harvard Medical School – Chief Information Officer
Further, with the litany of grant opportunities that you've outlined that will supplement the work, that will accelerate the implementation guidance and the reference implementations and the research, I think a combination of the guidance we come up with, the feedback from our workgroups, and the grant output will get us rapidly to where we need to be. So I think we just have our work ahead, and look forward to working with you guys to make sure we get it all done.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Thank you, John, for those comments. Before I turn to David Blumenthal for final comments, it strikes me that I share your optimism, and I'm actually not hopeful, but optimistic, as those words are actually not semantically interoperable. Hope is a feeling. Optimism is a feeling based on data, and so I believe that I have the data to share with Wes and others' optimism about what is ambitious, yet I would hope, in the current context for a variety of reasons, achievable. With that, let me turn to David for any final thoughts.

David Blumenthal – Department of HHS – National Coordinator for Health IT
I think, both hope and optimism are based on brain transmitters in sufficient quantity, not to be reductionistic about it. I think we actually have still one more thing to do, don't we? We have to take public comment.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Yes, we do.

David Blumenthal – Department of HHS – National Coordinator for Health IT
So I don't want to bring the curtain down because we've still got to hear from the public, but there have been a lot of nice things said, and I think I appreciate them all, and you should feel proud of yourselves as well. Washington is a town with a short memory, so we'll have to prove ourselves all over again in the next round in 2013, but we'll do so with a track record and with a way of operating together that I think will take us forward.

You know, when we started this seven or eight months ago, we didn't have the kind of – we hadn't gelled the way we have now, and that's a big advantage. I'm going to turn it back to Jon to take us through the public comments.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Terrific. Indeed, that closes one piece of our session, but in fact, in many ways, the very most important is the public comment. Let me turn to Judy Sparrow indeed to give us instructions for online comment and in person.

Judy Sparrow – Office of the National Coordinator – Executive Director
Great. Just a reminder, anybody in the room who cares to make public comment, please come to the microphone. Those on the phone, you can just press star, one, and the operator will queue you up. Finally, if you're on the Web, you need to call a number, which I can't see right now, but I think you can see it on here. It's 1-877-705-6006, and we'll begin in the room with Richard Singerman.

Richard Singerman – BioQuest – President
Richard Singerman. One thing I noticed from reading the IFR is it seemed like the consumer perspective, those requirements and standards for the consumer, call it PHR or access, consumer access to the EHR, were kind of coming later, and that stuck out to me, and I don't know if that was intentional just because PHRs aren't quite ripe yet. But if you look at an organization like Group Health, they actually adopted the Epic of PHR before the actual EHR, and they actually had a tremendous uptake initially, and that actually facilitated their internal, true EHR adoption. Given that you have a modular approach for EHR adoption, it could be very interesting to say, could you seed one or two consumer applications early, not the full thing, but maybe lab availability.

I know from the experiences of the VA, it's very attractive to consumers to get those results right away. And so not only do you feed more consumer happiness that way early on, but the consumers are a whole other incentive. You have the fiscal incentive side, but if you look at adoption and innovation, there's the

whole, well, what is my patient saying to me? If the patients get more excited about certain modules, it's a whole other pull on the innovation adoption approach, so I would just encourage a second look at that consumer focus and how that could benefit not only consumers, but accelerate physician and provider adoption.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you very much. We do not have anybody on the telephone. Aneesh?

Aneesh Chopra – White House – CTO
I would just like to ask a little bit of a question there. The 2011 provisions around the consumer access to the summary within 48 hours and so forth are in the reg, proposed rule. I'm just curious what consumer provisions were you thinking were missed. Your philosophical logic is precisely why it was in there. I'm curious what we missed.

Richard Singerman – BioQuest – President
I guess when I was reviewing them, I remember seeing, and I don't have them in front of me because I highlighted them. I remember that there were some other standards that were coming down the pike more around 2013 and 2015, and so it just seemed like the more front loaded that you could be, because I recall them kind of being phased in, so I couldn't tell you right now which ones were exactly 2011 versus 2013. But I remember that kind of jumped out at me that there were some things that seemed relatively simple to do a little bit earlier than later.

Jonathan Perlin – Hospital Corporation of America – CMO & President
The way that I read it that ONC was actually fairly aggressive. They didn't actually say you could give a report or an electronic copy. They said you could give a report and an electronic copy, which meant the CCR or CCD had to be used at each office visit, at each transition of care, and for inpatients. So when a number of my folks looked at that, they said, oh my, God.

Aneesh Chopra – White House – CTO
May I ask a question? Is there a way we could Socratic method Steve? Have you given any thoughts from a consumer empowerment perspective as to the bundle of goods that are asked for in 2011?

Steve Findlay – Consumers Union – Senior Healthcare Policy Analyst
I think we got as much as we were going to possibly get in 2011. I think it's progressive, and I think we're all interested in doing more in 2013 and 2015, and your comment is timely, as we think about the future. I think we're going to get it in there.

Jonathan Perlin – Hospital Corporation of America – CMO & President
We had forced that point … I think we talked about coordinating communication amongst members of the health team, but if we don't say it explicitly, I hope it's understood that team centrally includes the patient, and that reminder is always well taken. Look forward to continuing dialog and work about how that's translated into the standards and specification. Judy, other--?

Judy Sparrow – Office of the National Coordinator – Executive Director
There's nobody on the line, so I'll turn it back to you.

Jonathan Perlin – Hospital Corporation of America – CMO & President
Well, that concludes then today's session, and simply thanks, all. Indeed, I guess the official number is nine months, and I think people worked about as fast as they possibly could to deliver this baby. The nine-month metaphor is there. We've got a lot of work, and from Doug and John Glaser's comments, it

sounds like there's another delivery that's expected, so I hope you had restful holidays and look forward to the next meeting. Thanks, all, for your work, and thanks again to ONC staff for all of your work.

John Halamka – Harvard Medical School – Chief Information Officer
Look forward to the workgroup calls. Talk to you soon.